UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

UNITED STATES OF AMERICA *ex rel.* JOSEPH IBANEZ AND JENNIFER DERRICK,	:	Civil Action No. 1:11-CV-029
	:	Judge William O. Bertelsman
BRINGING THIS ACTION ON BEHALF OF THE UNITED STATES OF AMERICA, THE STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, ILLINOIS, HAWAII, INDIANA, IOWA, LOUISIANA, MARYLAND, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, WASHINGTON, WISCONSIN, THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA, AND THE DISTRICT OF COLUMBIA,	:	**FILED UNDER SEAL** Pursuant to 31 U.S.C. § 3730(b)(2) and Local Rule 3.2
	:	**DO NOT SERVE**
Plaintiffs and Relators,	:	
v.	:	
BRISTOL-MYERS SQUIBB COMPANY c/o Registered Agent The Corporation Trust Company No. 1209 Orange Street Wilmington, Delaware	:	
and	:	
OTSUKA AMERICA PHARMACEUTICAL, INC. c/o Registered Agent The Corporation Trust Company No. 1209 Orange Street Wilmington, Delaware	:	
Defendants.	:	

FIRST AMENDED COMPLAINT

I. INTRODUCTION.

1. *Qui Tam* Relators Joseph Ibanez and Jennifer Derrick bring this action on their own behalf and on behalf of the United States of America, the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Illinois, Hawaii, Indiana, Iowa, Louisiana, Maryland, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Washington, Wisconsin, the Commonwealths of Massachusetts and Virginia, and the District of Columbia to recover damages and penalties arising from Defendants Bristol-Myers Squibb's ("BMS") and Otsuka America Pharmaceutical, Inc.'s ("Otsuka") violations of the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq*., and the respective state FCAs. The violations arise out of requests for payment submitted to Medicaid, Medicare, TRICARE, and other federal- and state-funded government healthcare programs (hereinafter collectively referred to as "government healthcare programs").

2. Relators allege that the Defendants marketed the prescription drug Abilify for off-label use in Medicare, Medicaid and other government healthcare beneficiaries, including in children and elderly people, in direct contravention of Corporate Integrity Agreements with the United States in which Defendants promised not to engage in off-label marketing. Abilify is an atypical anti-psychotic drug originally indicated only for schizophrenia and bipolar disorder in adults. In November 2007, Abilify was approved for labeling as an adjunctive treatment for major depressive disorder (MDD) in adults. Abilify has never been indicated for depression in child or adolescent patients, and only received a limited child or adolescent indication in late 2007, when it was indicated for

schizophrenia in adolescents aged 13 to 17 years. It was later indicated for bipolar 1 disorder in pediatric patients aged 10 to 17 years and irritability related to autistic disorders for pediatric patients ages 6 to 17 years. Abilify contains Black Box warnings for elderly patients with dementia and children and adolescents with MDD.

3. Despite the limited, approved indications and the serious warnings, Defendants knowingly and vigorously marketed Abilify to child, adolescent, geriatric and other providers for uses outside the label indications and for which there was no credible scientific basis to assert safety and efficacy for such uses. Defendants planned and executed their illegal marketing plan with the purpose of inducing physicians to prescribe Abilify for off-label uses.

4. Defendants induced physicians to prescribe Abilify in multiple ways, including by illegally incentivizing providers in violation of the Anti-Kickback Statute.

5. Defendants' conduct violated material conditions of payment of claims for Abilify and, if known, would have affected the federal and state governments' decision to pay the claims.

6. Defendants intended and knew that their conduct caused submission of claims to government healthcare programs of Abilify prescriptions which were ineligible for reimbursement.

7. The off-label uses for which Defendants marketed Abilify are not supported as medically acceptable by any major compendia such as those specified by 42 U.S.C. §1396r-8(g)(1)(B)(I) (describing federal Medicaid drug coverage); and not used in the treatment of a rare disease or condition for which it was FDA-approved or, alternatively, supported by reliable evidence as set forth in 32 C.F.R. §199.2 and

TRICARE Policy Manual, Chapter 7, Section 2.1 (describing TRICARE drug coverage).

8. The illegal promotional campaigns and kickback schemes are specifically prohibited by Corporate Integrity Agreements between Defendants and the United States in 2007 and 2008. Instead of refraining from further off-label promotion and illegal incentive schemes, as required by the Corporate Integrity Agreements, Defendants continued to vigorously to market Abilify in illegal ways.

9. Relators also seek to recover damages arising from Defendant BMS's wrongful termination of Relators' employment in violation of the anti-retaliation provisions of the FCA.

II. JURISDICTION AND VENUE.

10. This action arises under the United States Civil False Claims Act, 31 U.S.C. § 3729 *et seq*., and the False Claims Acts of the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Illinois, Hawaii, Indiana, Iowa, Louisiana, Maryland, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Washington, Wisconsin, the Commonwealths of Massachusetts and Virginia, and the District of Columbia.

11. The Court has subject-matter jurisdiction pursuant to 31 U.S.C. § 3732 (a)-(b) and 28 U.S.C. § 1331, and has personal jurisdiction over the Defendants because the Defendants do business and are located in this district.

12. Venue lies under 28 U.S.C. 1391 (b), (c) and 31 U.S.C. 3732 (a) because Defendants operate and transact business within this district.

13. The allegations of this Complaint have not been publicly disclosed in a criminal, civil, or administrative hearing, nor in any congressional, administrative, or General Accounting Office report, hearing, audit, or investigation, nor in the news media.

14. Relators are original sources of the information upon which this Complaint is based, as that phrase in used in the False Claims Act and other laws at issue herein.

15. Relators provided disclosure of the allegations of this Complaint to the United States and the respective states prior to filing under the federal False Claims Act and state False Claims Acts, respectively.

III. PARTIES.

16. The real parties in interest to the claims of this action are the United States of America, the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Illinois, Hawaii, Indiana, Iowa, Louisiana, Maryland, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Washington, Wisconsin, the Commonwealths of Massachusetts and Virginia, and the District of Columbia.

17. Relator Joseph Ibanez is a resident of Ohio. He worked as a sales representative for BMS from 2001 through his wrongful termination on or about July 23, 2010. In 2005, Relator Ibanez was assigned to market Abilify in the BMS Residential Care Division. In October 2007, when that division dissolved, he was assigned to the Neuroscience Division, Account-Based Sales (ABS) of Abilify. In October 2009, when Neuroscience was again re-organized, Relator Ibanez became a Pediatric-Focused Specialist (PFS) for Abilify.

18. Relator Jennifer Derrick is a resident of Arizona. She worked as a sales representative for BMS from April 1988 through August 1996, and from November 2005 through her wrongful termination on May 12, 2010. In 2005, Relator Derrick was assigned to the sale of Abilify in the Residential Care Division. In October 2007, when that division dissolved, she was assigned to the Neuroscience Division, Office-Based Sales (OBS) of Abilify. She remained in OBS when Neuroscience was again re-organized in October 2009, until her termination in May 2010.

19. Defendant Bristol-Myers Squibb is a pharmaceutical company with its corporate headquarters in New York City, New York. It is incorporated in Delaware and transacts business nationwide, including in this district.

20. Defendant Otsuka is a pharmaceutical company headquartered in Tokyo, Japan, with U.S. offices in Rockville, Maryland, Princeton, New Jersey, Maple Grove, Minnesota and Redwood City, California. It is incorporated in Delaware and transacts business nationwide, including in this district.

IV. RULE 9(b), FED. R. CIV. P. ALLEGATIONS.

21. Much of the documentary evidence necessary to prove the allegations in this Complaint is in the exclusive possession of either the Defendants or the United States.

22. With respect to each allegation herein made upon information and belief, Relators have, based upon their knowledge, data, and experience, a reasoned factual basis to make the allegation but lack complete details of it.

23. Relators are familiar with the policies and practices alleged herein as a result of their employment relationship with Defendant BMS and their personal

observations of the conduct of both BMS and Otsuka in improperly inducing sales of Abilify through illegal marketing of off-label uses and illegal incentives in violation of the Anti-Kickback Statute.

24. However, Relators do not have access to all of the information regarding the claims for payment caused to be submitted by Defendants. This information is in the exclusive possession and control of the Defendants and the United States or the States.

25. Defendants have caused to be submitted and, on information and belief, continue to cause submission of, false claims to government healthcare programs for payment of Abilify for noncovered and nonpayable uses.

26. Defendants' scheme has been in place since 2005 and is ongoing.

V. THE STATUTORY AND REGULATORY ENVIRONMENT.

A. Overview: Drug Coverage under Federal Healthcare Programs.

27. Congress has the authority to decide which drugs and uses will be paid for by federal healthcare programs. As alleged below, Congress has exercised this authority in very specific and considered ways regarding each federal program. For "covered outpatient drugs," as that term is defined by statute, Congress has integrated FDA drug restrictions into federal health program restrictions regarding what drugs will be covered and paid.

28. Congress has not delegated direct authority to the FDA to decide which drugs and uses will be paid by federal healthcare programs. Instead, the FDA's primary function with respect to drugs and their uses is to receive, evaluate and approve or disapprove specific labels under the 1966 Fair Packaging and Labeling Act, 15 U.S.C. §

1451. Another FDA function is to monitor and enforce manufacturers' compliance with advertising and promotional restrictions under the Food, Drug, and Cosmetics Act ("FDCA") and the Food and Drug Administration Modernization Act of 1997 ("FDAMA").

29. Under the FDCA, pharmaceutical drug companies cannot distribute a drug in interstate commerce unless the FDA has approved its use. 21 U.S.C. §§ 355(a) & (d). After extensive testing, the FDA may approve a pharmaceutical drug for one or more specific uses and will establish a recommended dosage for those uses. Use of an approved drug for any purposes other than those specifically approved by the FDA is referred to as an "off-label" use. The FDCA does not prohibit physicians from prescribing an FDA approved drug for unapproved off-label uses. The FDCA does, however, specifically prohibit drug manufacturers from marketing or promoting a drug for off-label uses. 21 U.S.C. §§ 331 & 352.

30. Federal and state health care programs establish conditions under which they will pay for prescription drugs dispensed to beneficiaries. As alleged more specifically below, these conditions incorporate the FDCA restrictions to define the drugs which will be covered and reimbursed by public healthcare programs. As a general rule, federal and state health care programs do not reimburse the cost of drugs prescribed for off-label uses.

31. As such, the knowing and undisclosed failure to comply with FDCA regulations regarding the marketing of approved uses of drugs will cause federal and state governments to pay out benefits they did not intend for noncovered and nonpayable drugs.

32. The details of each of the relevant statutory and regulatory systems are included below.

B. The FDA Regulatory System.

33. Under the FDCA, 21 U.S.C. §§ 301-97, new pharmaceutical drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of the FDA that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a), (d). Approval of the drug by the FDA is the final step in a multi-year process of study and testing, and pharmaceutical concerns initiate the approval process by filing a New Drug Application ("NDA").

34. The FDA does not approve a drug for treatment of sickness in general. Instead, a drug is approved for treatment of specific conditions, for which the drug has been extensively tested in animal subjects and human patients. Each specific approved use is called an "indication" for which the drug may be prescribed. The FDA specifies particular dosages determined to be safe and effective for each indication.

35. The indication and dosages approved by the FDA are set forth in the drug's labeling, the content of which is also closely reviewed by the FDA. 21 U.S.C. §§ 352, 355(d). An example of the drug's labeling is the printed insert in the drug's packaging. The FDA only approves the NDA if the labeling conforms to the uses and dosages that the FDA has approved. 21 U.S.C. § 355(d).

36. Under the FDAMA, if a manufacturer wishes to market or promote an approved drug for additional uses – *i.e.*, uses not listed on the approved label – the manufacturer must perform additional clinical trials similar to those which supported the initial approval, and then submit a supplemental NDA, or "sNDA." 21 U.S.C. §

360aaa(b), (c). Until approval of the new indication or dose, it is off-label and cannot be the subject of marketing efforts. Off-label marketing restrictions are an important patient-safety feature of the FDAMA because these restrictions maintain a manufacturer's incentive to engage in appropriate testing and apply for additional indications rather than skirt FDA review.

37. "Off-label" refers to the use of an approved drug for any purpose, or in any manner, other than the indications approved by the FDA and described in the drug's labeling. Off-label use includes treating a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified in the label, or treating a different patient population (e.g., treating a child when the drug is approved to treat adults).

38. Although the FDA is responsible for ensuring that a drug is safe and effective for the specific approved indication, it does not regulate the practice of medicine.

39. Although physicians may prescribe drugs for off-label usage, the law prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved, or for a patient group the FDA has not approved. A manufacturer illegally misbrands a drug if the drug's labeling (which includes all marketing and promotional materials relating to the drug) describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331, 352.

40. In addition to prohibiting manufacturers from directly marketing and promoting a drug's unapproved use, Congress and the FDA have also sought to prevent manufacturers from employing indirect methods to accomplish the same end.

For example, the FDA regulates two of the most prevalent indirect promotional strategies: (1) manufacturer dissemination of medical and scientific publications concerning the off-label uses of their products; and (2) manufacturer support for Continuing Medical Education ("CME") programs that focus on off-label uses.

41. With regard to the first practice – disseminating written information – the FDAMA prohibits manufacturers from disseminating information regarding off-label usage unless it receives an "unsolicited request from a health care practitioner." 21 U.S.C. § 360aaa-6. In any other circumstance, a manufacturer may not disseminate information concerning the off-label uses of a drug unless it has submitted an application to the FDA seeking approval of the drug for the off-label use; has provided the materials to the FDA prior to dissemination; and the materials themselves are submitted in unabridged form and are neither false nor misleading. 21 U.S.C. §§ 360aaa(b) & (c); 360aaa-1.

42. The off-label regulatory regime protects patients and consumers by ensuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific governmental body – the FDA.

43. While the FDA has authority to enforce compliance with its advertising and promotional restrictions for the purpose of protecting the public, it has no authority to redress violations by manufacturers, whether to protect federal healthcare programs against false claims or remedy such claims already submitted.

C. <u>The Anti-Kickback Statute.</u>

44. Under the Medicare and Medicaid Patient Protection Act, 42 U.S.C. § 1320a-7b(b) (the "Anti-Kickback Statute" or "AKS"), it is unlawful to knowingly offer or

pay any remuneration in cash or in kind in exchange for the referral of any product for which payment is sought from any federally-funded health care program, including Medicare, Medicaid, and TRICARE. Violation of the statute can subject the perpetrator to criminal and civil penalties, as well as exclusion from participation in federally-funded healthcare programs.

45. The AKS also provides that claims arising out of violations of its provisions are false claims. A claim "that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim" for purposes of the False Claims Act. 42 U.S.C § 1320a-7b(g).

46. The AKS is designed to, *inter alia*, ensure that patient care will not be improperly influenced and corrupted by compensation arrangements which are not directly related to the care of patients or which influence patient care decisions.

47. Payment of remuneration of any kind violates the statute if one of the purposes of the payment is to induce referrals, and remuneration offered or paid in return for the promise to send patients to a particular provider or facility qualifies as a kickback. Giving a person the opportunity to earn money for referring patients may also constitute an inducement under the AKS.

48. Government health care programs require every provider who seeks payment to sign Provider Agreements in order to establish their eligibility to seek reimbursement. Every physician described in this complaint signs a provider agreement with the United States certifying that:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to [me]. The Medicare laws, regulations, and program instructions are available through the [Medicare] contractor. I understand that payment of a claim by Medicare is conditioned upon the

> claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal Anti-Kickback Statute and the Stark law), and on the [provider's] compliance with all applicable conditions of participation in Medicare.

Form CMS-855.

49. Compliance with the AKS is a condition of payment of all claims submitted for reimbursement by Medicaid, Medicare, and other government healthcare programs.

50. Compliance with the AKS is a condition of payment of all claims submitted for reimbursement by Medicaid, Medicare, and other government healthcare programs.

D. Prescription Drug Payment Under Federal Health Care Programs.

1. The Medicaid Program.

51. Medicaid is a public assistance program providing for payment of medical expenses for approximately 55 million low-income patients. Funding for Medicaid is shared between the federal government and state governments. The Medicaid program subsidizes the purchase of more prescription drugs than any other program in the United States.

52. Federal reimbursement for prescription drugs under the Medicaid program is limited to "covered outpatient drugs." 42 U.S.C. §§ 1396b(I)(10), 1396r-8(k)(2), (3).

53. Under the Medicaid statute, a "covered outpatient drug" includes a drug dispensed by prescription and approved as safe and effective under the FDCA, 21 U.S.C. §§ 355 & 357, but does not include "a drug or biological used for a medical indication which is not a medically accepted indication." 42 U.S.C. § 1396r-8(k)(2), (3).

54. The statute defines "medically accepted indication" as:

> any use for a covered outpatient drug which is approved under the [FDCA], or the use of which is supported by one or more citations included or approved for

> inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this section.

Id. at § 1396r-8(k)(6). The three compendia described in subsection (g)(1)(B)(i) are the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information (and its successor publications), and the Drugdex Information System. *Id*. at § 1396r-8(g)(1)(B)(i).

55. In addition to on-label uses, whether an FDA-approved drug is listed in one or more of these three compendia for a particular indication determine whether a prescription for that use may be reimbursed under Medicare and Medicaid and other federal health care programs.

56. In order to participate in the Medicaid program, a State must have a plan for medical assistance that has been approved by the CMS, which administers the program on behalf of the Secretary of Health and Human Services. The state plan must specify, among other things, the specific kinds of medical care and services that will be covered. 42 U.S.C. § 1396a(a)(10), (17). If the plan is approved by the Secretary, the State thereafter is eligible for federal financial participation, i.e., reimbursement by the federal government for a specified percentage of the amounts that qualify as medical assistance under the state plan. Id. at §§ 1396b(a)(1), 1396d(b).

57. States are accorded broad flexibility in tailoring the scope and coverage of their plans. While the Medicaid Act requires States to provide certain basic services, the Act permits, but does not require, States to cover prescription drugs, although most States choose to do so. 42 U.S.C. § 1396d(a)(12).

58. In 1990, Congress enacted the Medicaid Drug Rebate Statute, codified at 42 U.S.C. §1396r-8, to “establish a rebate mechanism in order to give Medicaid the

benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser." H.R. Rep. No. 881, 101st Cong., 2d Sess. 96 (1990). That statute prohibits federal financial participation for covered outpatient drugs unless there is a rebate agreement in effect under section 1396r-8. 42 U.S.C. §§ 1396b(i)(10)(A) and 1396r-8(a)(1).

59. Once a drug manufacturer has entered into a rebate agreement for a covered outpatient drug, a State is generally required to cover that drug under the state plan. However, there are several provisions of the Medicaid Act that permit a State to exclude or restrict coverage. 42 U.S.C. § 1396a(a)(54); H.R. Rep. No. 881 at 97, 98.

60. A State may exclude or restrict coverage of a drug where "the prescribed use is not for a medically accepted indication," *i.e*., a use which is not listed in the labeling approved by the FDA, or which is not included in one of the drug compendia identified in the Medicaid statute. 42 U.S.C. § 1396r-8(k)(6); § 1396r-8(d)(1)(B)(i). Most states restrict coverage of drugs in accord with the Social Security Act, including the federal restrictions on medically-accepted indications.

61. State Medicaid agencies administer Medicaid and reimburse pharmacies for drugs, which submit claims on behalf of individual Medicaid beneficiaries. The State agencies in turn submit claims to the United States for the federal financial participation ("FFP") of claims submitted on behalf of Medicaid beneficiaries.

62. Medicaid claims, depending on the circumstances, may be submitted by pharmacies electronically or on paper, but in most cases use a standard Form, such as the CMS-Form 1500, or other similar claim form (in Florida, for example, a "Universal

Claim Form" is used) which records, among other things, the identity of the beneficiary, the provider, and the drug.

63. Drugs are identified on Medicaid claims and the Medicaid computer system drug file by the National Drug Code ("NDC"). The NDC is an 11-digit number. The first 5 digits identify the manufacturer or supplier, the next 4 digits identify the product, and the last 2 digits identify the package size.

2. The Medicare Program.

64. The Medicare Prescription Drug Improvement and Modernization Act of 2003 added prescription drug benefits to the Medicare program. Medicare serves approximately 43 million elderly and disabled Americans.

65. The first stage of the Medicare program, from May 2004 through December 2005, permitted Medicare beneficiaries to enroll in a Medicare-approved drug discount card program.

66. In addition, low-income beneficiaries, defined as those whose incomes are not more than 135% of the poverty line (those with incomes of no more than $12,569 for a single person or $16,862 for a married couple in 2004) qualified for a $600 credit (funded by Medicare) on their drug discount card for 2004 and again for 2005.

67. Starting in January 2006, Part D of the Medicare Program provided subsidized drug coverage for all beneficiaries, with low-income individuals receiving the greatest subsidies.

68. For those beneficiaries with dual eligibility under both Medicare and Medicaid, their prescription drugs are covered exclusively under Medicare Part D.

Thus, the responsibility for providing pharmacy benefits for dually eligible beneficiaries was transferred from Medicaid to Medicare Part D on January 1, 2006.

69. The Part D prescription drug program provides comparable benefits and exclusions as the Medicaid program.

70. Specifically, a Part D covered drug is available only by prescription, if approved by the FDA (or is a drug described under section 1927(k)(2)(A)(ii) or (iii) of the Social Security Act), used and sold in the United States, and used for a medically accepted indication (as defined in section 1927(k)(6) of the Act). A covered Part D drug includes, *inter alia*, prescription drugs.

71. The definition of a covered Part D drug specifically excludes drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid under section 1927(d)(2) of the Act, with the exception of smoking cessation agents.

72. Medicare Part D is administered through CMS, with coverage provided through private drug plans. Plan sponsors are authorized to negotiate independently pharmacy reimbursement and price concessions with manufacturers and pharmacies, and then to seek reimbursement from Medicare.

73. All plan sponsors are required to have a comprehensive plan to detect, correct and prevent fraud, waste and abuse. The specific requirements of the compliance program for the Part D benefit includes directions to specific kinds of fraud and abuse in violation of program requirements, such as non-compendia drug payments.

74. For example, the Prescription Drug Benefit Manual ("PDBM") issued by CMS identifies an example of Sponsor fraud, waste and abuse as "Non-compendia payments: Payments for Part D drugs that are not for a 'medically accepted indication.'" PDBM, Ch. 9, § 70.1.1. The PDBM further specifically identifies an example of pharmaceutical manufacturer fraud, waste and abuse as "Illegal Off-Label Promotion: Illegal promotion of off-label drug usage through marketing, financial incentives, or other promotional campaigns." PDBM, Ch. 9, § 70.1.6.

75. Medicare may also pay for prescription drugs for inpatients through other parts of the program, but does not pay for non-medically indicated drugs under any aspect of its prescription drug coverage.

3. Reimbursement Under Other Federal Health Care Programs.

76. In addition to Medicaid and Medicare, the federal government reimburses a portion of the cost of prescription drugs under several other federal health care programs, including but not limited to, CHAMPUS/ TRICARE/CHAMPVA, the Federal Employees Health Benefit Program, the Indian Health Service, and the Railroad Retirement Medicare Program.

77. CHAMPUS/TRICARE, administered by the United States Department of Defense, is a health care program for individuals and dependents affiliated with the armed forces. CHAMPVA, administered by the United States Department of Veterans Affairs, is a health care program for the families of veterans with 100 percent service-connected disabilities. The Federal Employee Health Benefit Program, administered by the United States Office of Personnel Management, provides health insurance for federal employees, retirees, and survivors. The Indian Health Service, administered by

the Department of Health and Human Services, provides health services to Native Americans. The Railroad Retirement Medicare program, administered through the United States Railroad Retirement Board, provides Medicare coverage to retired railroad employees.

78. Coverage for off-label prescription drugs under these programs is similar to coverage under the Medicaid program, consistent with the regulatory framework under the FDCA. *E.g.*, 32 C.F.R. Part 199; TRICARE Policy Manual 6010.47-M, Chapter 7, Section 7.1 (B)(2) (March 15, 2002); CHAMPVA Policy Manual, Chapter 2, Section 22.1, Art. II (A)(2) (June 6, 2002).

79. Reimbursement for drugs under these programs may occur either through direct purchase of drugs later administered at government facilities or through coverage of drugs administered by other providers to veterans and members of the armed forces eligible for benefits under these programs.

E. Claims Caused to Be Submitted For Off-Label Non-Compendium Usage Of Abilify Are False Claims.

80. As a condition of payment of Medicare, Medicaid and other government healthcare programs, claims can only be submitted for "covered outpatient drugs," that are the subject of a rebate agreement with a pharmaceutical manufacturer. To be covered, drugs must be used for a medically-accepted indication, including a use approved by its label or approved by published compendia authorized by the Medicaid statute.

81. Because those programs specifically exclude coverage and reimbursement for off-label non-compendia uses of drugs, claims submitted for such drugs prescribed for such uses violate statutory pre-conditions of payment.

82. Claims submitted to federal and state healthcare programs in violation of conditions of payment are false claims. Submission of such claims materially misrepresents that the claims are eligible for reimbursement consistent with applicable statutes and regulations, and results in the payment disbursement of public funds never intended to be used for that purpose.

83. Defendants' violations would have affected the Government's decision to pay the claims.

84. As alleged below, Defendants illegally marketed and promoted Abilify for off-label, non-compendia use. The off-label uses of Abilify were neither approved by the FDA nor included in any of the drug compendia specified by the Medicaid statute. Rather, indications listed on the FDA-approved label and the authorized compendia for Abilify are identical.

85. As a result of Defendants' illegal marketing campaign, claims have been submitted for Abilify in material violation of conditions of payment of the claims.

86. Defendants' illegal actions were the substantial factor in causing the submission of claims in violation of known conditions of payment.

87. Defendants' illegal off-label marketing campaign was the driving factor causing the submissions for reimbursement for Abilify to Medicare, Medicaid and other healthcare programs for non-reimbursable uses.

88. Thus, every claim which Defendants caused to be submitted for non-medically-indicated uses of Abilify is a false claim. Defendants' knowing conduct in causing the submission of such claims violated the False Claims Act.

F. Corporate Integrity Agreement Between the United States and BMS.

89. BMS has long been aware that its illegal actions caused false claims for Abilify to be submitted to Medicare, Medicaid, and other federal healthcare programs. In addition to its obligation to know and to comply with the law in order for its drugs to be covered by those programs, BMS entered into an Agreement with the United States to police and certify its ongoing compliance with those laws as a condition of continued participation in such programs.

90. In September 2007, BMS entered into a five-year Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("the 2007 CIA").

91. In the 2007 CIA, BMS promised the United States that it would establish and maintain a compliance program, develop and implement a business code of conduct for all employees, and ensure its policies and procedures addressed, among other things:

- appropriate ways to conduct Promotional and Product Services Related Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b), and the False Claims Act (codified at 31 U.S.C. 3729-3733);

- appropriate ways to conduct Promotional and Product Services Related Functions in compliance with all FDA requirements, including procedures governing the handling and/or response by sales representatives, Medical Science Liaisons, and Medical Information to requests for information about off-label uses;

- appropriate mechanisms by which the Medical Information Department receives and responds to requests for information about off-label uses of BMS's products, including but not limited to, the form and content of information disseminated by Medical Information in response to such requests and the internal review process for the information disseminated;

- call plan development for the Group's sales representatives for those Government Reimbursed Products having a high potential for off-label use that could be driven by detailing an inappropriate audience of HCPs [healthcare professionals] or institutions. ***For each such product, the Policies and Procedures shall require that BMS review the associated call plans and the bases upon which physician specialties and institutional provider types are included in, or excluded from, the call plans. The Policies and Procedures shall also require that BMS shall modify the call plans as necessary to ensure that BMS is promoting its products in a manner that complies with all applicable Federal health care program and FDA requirements. The call plan reviews shall occur at least annually and shall also occur each time when the FDA approves a new or additional indication for a product meeting the requirements set forth above;***

- consultant engagements entered into with HCPs (including, but not limited to, those engagements relating to speaker programs, speaker trainings, advisory boards, or any similar fee- for-service relationship with an HCP) and all events and expenses relating to such HCP engagements. These policies shall be designed to ensure that the consultant engagements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements.

2007 CIA, p.9, Section B.3, (emphasis supplied).

92. The 2007 CIA also contains detailed training and independent review requirements regarding BMS policies and procedures.

93. The 2007 CIA requires BMS to establish a Disclosure Program for its employees that includes a mechanism (a toll-free compliance telephone line) to enable individuals to disclose, to the Chief Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with BMS' s policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. This Program is required to emphasize a nonretaliation policy. 2007 CIA, p.20, Section E.

94. The 2007 CIA requires BMS to retain a surveying entity to review its detailing records, and to provide that information as part of an annual report to the OIG. 2007 CIA, p.25, Section J.

95. The 2007 CIA requires that the BMS Compliance Department has developed a Field Force Monitoring Program (FFMP) to evaluate and monitor US Pharmaceuticals Group sales representatives' interactions with HCPs. The FFMP is a formalized process designed to directly observe the appropriateness of sales representative interactions with HCPs and to identify potential off-label promotional activities. BMS compliance personnel conduct field observations of sales representatives to assess whether the messages delivered and materials distributed to HCPs are consistent with BMS compliance Policies and Procedures. This requirement provides for formal investigation of any identification of potential off-label promotion, and inclusion of such information in its annual reports to the OIG. 2007 CIA, pp.31-32, Section M.

96. BMS's annual reports to the OIG contain certifications by its Chief Compliance Officer that it is in compliance with the terms of the CIA and, among other things, that "BMS's promotional materials containing claims or information about Government Reimbursed Products and other materials and information intended to be disseminated outside BMS … are in compliance with the requirements of the Federal anti-kickback statute, the Prescription Drug Marketing Act, and other applicable laws and legal requirements." 2007 CIA, p. 39-40, Section C.

97. In the annual report, BMS also specifically certifies that its call plans for those Government Reimbursed Products subject to the requirements of the CIA were

reviewed by U.S. Healthcare Law Compliance at least once during the Reporting Period (consistent with the requirements of Section III.B.3.f of the CIA) and, for each such Government Reimbursed Product, the call plans were found to be consistent with BMS's policy objectives as referenced above in Section III.B.3.f. *Id.*

98. Under the CIA, a material breach of the CIA by BMS constitutes an independent basis for BMS's exclusion from participation in the Federal health care programs. 2007 CIA, p.46.

99. BMS agreed to the 2007 CIA as part of the settlement of a *qui tam* action alleging that BMS violated the FCA by marketing and promoting Abilify for off-label use, thereby causing false claims for such use to be submitted to federally-funded healthcare programs.

100. In the settlement of that case, also dated September 2007, the United States released its claims against BMS for the following Covered Conduct:

> The Government contends that, during the period from January 2002 through December 2005, BMS knowingly promoted the sale and use of Abilify (aripiprazole) for pediatric use (i.e., for patients younger than 18) and to treat dementia-related psychosis, uses for which the United States Food and Drug Administration ("FDA") has not approved Abilify. The Government contends that BMS knowingly and willfully offered and paid illegal remuneration in the form of consulting arrangement fees to physicians to prescribe Abilify. The Government contends that BMS's promotion of Abilify for pediatric use and to treat dementia-related psychosis violated the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 331(a) & (d). Furthermore, the Government contends that, during the relevant time period, these uses were not medically-accepted indications, as defined by 42 U.S.C. § 1396r-8(k)(6) (uses approved under the FDCA or included in or approved for inclusion in specified drug compendia), and that certain State Medicaid Programs did not cover Abilify dispensed for these uses. In addition, the Government contends that, during this time period, BMS knowingly caused false and/or fraudulent claims to be submitted to Medicaid, TRICARE, and FEHBP for Abilify, and caused the DVA and DOD to purchase Abilify, for pediatric use and for dementia-related psychosis.

Settlement Agreement, ¶ N.4.

101. The United States further released the claim that:

> during the period from January 1999 through December 2003, BMS knowingly and willfully offered and paid illegal remuneration to physicians, and to some physician assistants and nurse practitioners, through consulting fees and expenses for participating in National Consulting Conferences, Regional Consulting Conferences, Clinical Advisory Councils, District Advisory Boards, Interactive Training Sessions, Preceptorships, and similar consulting programs, in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2). The Government further contends that, during this time period, BMS knowingly caused the submission of false and/or fraudulent claims to Medicaid, Medicare, other federal health care programs, and caused DVA and the Department of Defense ("DOD") to purchase BMS drugs, by inducing these physicians, physician assistants, and nurse practitioners to prescribe and/or to recommend the prescribing of the BMS drugs listed in Attachment B [listing Abilify].

Settlement Agreement, ¶ N.3.

102. Notwithstanding this settlement and its ongoing obligations under the CIA, BMS continues to illegally promote Abilify for off-label uses and has done so continuously since the end of the Covered Conduct time frame (2005) and going forward.

103. BMS's false certifications to the United States contributed to the material misrepresentations made to the United States regarding the reimbursement for off-label, non-compendia uses of Abilify, in violation of conditions of payment for federal and state healthcare programs.

104. BMS's false statements caused false claims to be paid or approved by Medicare, Medicaid and other federal healthcare programs in violation of the FCA.

G. The Corporate Integrity Agreement Between the United States and Otsuka.

105. Similarly, Otsuka has long been aware that its illegal actions caused false claims for Abilify to be submitted to Medicare, Medicaid, and other federal healthcare programs. In addition to its obligation to know and to comply with the law in order for its drugs to be covered by those programs, Otsuka entered into an Agreement with the United States to police and certify its ongoing compliance with those laws as a condition of continued participation in such programs.

106. In March 2008, Otsuka entered into a five-year Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("the 2008 CIA").

107. In the 2008 CIA, Otsuka promised the United States that it would establish and maintain a compliance program, develop and implement a business code of conduct for all employees, and ensure its policies and procedures addressed, among other things:

- appropriate ways to conduct Promotional and Product Services Related Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b), and the False Claims Act (codified at 31 U.S.C. 3729-3733);

- appropriate ways to conduct Promotional and Product Services Related Functions in compliance with all FDA requirements, including procedures governing the handling and/or response by sales representatives, Medical Science Liaisons, and Medical Information to requests for information about non-FDA approved (off-label) uses;

- the mechanisms through and manner in which Otsuka receives and responds to requests for information about off-label uses of Otsuka's products; the form and content of information disseminated by Otsuka in response to such requests and the internal review process for the information disseminated.

- development of sales call plans for Government Reimbursed Products. ***For each product, the Policies and Procedures shall require that Otsuka review the call plans for the product and the bases upon which specified physician specialties and institutional provider types are included in, or excluded from, the call plans. The Policies and Procedures shall also require that Otsuka modify the call plans as necessary to ensure that Otsuka is promoting its products in a manner that complies with all applicable Federal health care program and FDA requirements. The call plan reviews shall occur at least annually and shall also occur each time when the FDA approves a new or additional indication for a Government Reimbursed Product;***

- consultant engagements or fee-for-service arrangements entered into with HCPs or HCIs (including, but not limited to, speaker programs, speaker trainings, advisory boards, or any similar relationship with an HCP or HCI) and all events and expenses relating to such engagements or arrangements. These policies shall be designed to ensure that the engagements or arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements.

2008 CIA, pp.5-8 Section III(B))(2), (emphasis supplied).

108. The 2008 CIA also contains detailed training and independent review requirements regarding Otsuka policies and procedures.

109. The 2008 CIA requires Otsuka to establish a Disclosure Program for its employees that includes a mechanism (a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Otsuka' s policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. This Program is required to emphasize a nonretaliation policy. 2008 CIA, p.15, Section E.

110. The 2008 CIA requires Otsuka to engage one or more OIG-approved Independent Review Organizations (IRO), such as an accounting, auditing, or consulting firms, to perform reviews to assist in assessing and evaluating Promotional and Product Services Related Functions. The IRO shall conduct reviews that assess Otsuka's systems, processes, policies, procedures, and practices relating to Promotional and Product Services Related Functions. The IRO and Otsuka shall retain and make available to the OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Otsuka) related to the reviews. 2008 CIA, p. 12, Section D(1)(a)-(c); Appendix A.

111. The 2008 CIA requires that Otsuka continue with its Field Force Monitoring Program (FFMP), developed to evaluate and monitor sales representatives' interactions with HCPs. The FFMP is a formalized process designed to directly observe the appropriateness of sales representative interactions with HCPs and to identify potential off-label promotional activities. The FFMP requires that Otsuka District Managers conduct field observations of all sales representatives to assess whether targeted physicians treat patients with approved indications for the Otsuka product. If not, the District Manager must notify the Compliance Officer and the Vice President for Sales and request that the physician be removed from the call list, and must instruct the sales representative to discontinue calling on the physician. This requirement provides for formal investigation of any identification of potential off-label promotion, and inclusion of such information in its annual reports to the OIG. 2008 CIA, pp.19-20, Section J.

112. Otsuka's annual reports to the OIG contain certifications by its Compliance Officer that it is in compliance with the requirements of the CIA and, among other things that "Otsuka's promotional materials containing claims or information about Government Reimbursed Products and other materials and information intended to be disseminated outside Otsuka … are in compliance with the requirements of the Federal anti-kickback statute, the Prescription Drug Marketing Act, and other applicable laws and legal requirements." 2008 CIA, p. 26, Section C.

113. In the annual report, Otsuka also specifically certifies that its call plans for those Government Reimbursed Products were reviewed at least once during the Reporting Period (consistent with the requirements of Section III.B.3.f of the CIA) and, the call plans were found to be consistent with Otsuka's policy objectives as referenced above in Section III.B.3.e. *Id.*

114. Under the CIA, a material breach of the CIA by Otsuka constitutes an independent basis for Otsuka's exclusion from participation in the Federal health care programs. 2008 CIA, p.32.

115. Otsuka agreed to the 2008 CIA as part of the settlement of a *qui tam* action alleging that Otsuka violated the FCA by marketing and promoting Abilify for off-label use, thereby causing false claims for such use to be submitted to federally-funded healthcare programs. Notwithstanding this settlement and its ongoing obligations under the CIA, Otsuka continues to illegally promote Abilify for off-label uses and has done so continuously since the end of the 2005 and going forward.

116. Otsuka's false certifications to the United States contributed to the material misrepresentations made to the United States regarding the reimbursement for

off-label, non-compendia uses of Abilify, in violation of conditions of payment for federal and state healthcare programs.

117. Otsuka's false statements caused false claims to be paid or approved by Medicare, Medicaid and other federal healthcare programs in violation of the FCA.

H. The FDA-Approved Indications For Abilify.

118. Abilify (aripiprazole) is an atypical antipsychotic drug. In November 2002, FDA approved labeling indicating Abilify for treatment of schizophrenia in adults.

119. In September 2004, FDA approved an indication for Abilify for treatment of acute manic and mixed episodes associated with bipolar disorder in adults.

120. In April 2005, the FDA issued a Public Health Advisory that it had determined that increased mortality was associated with the use of atypical second generation anti-psychotic medications, including Abilify, for behavioral disorders in elderly patients with dementia

121. In February 2006, the FDA required the inclusion of a boxed warning on the label, also known as a "black box," advising that Abilify had been associated with "INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS."

113. This label is called a "black box" warning because of the heavy black line which surrounds the warning contained therein, a black-box warning is the most serious of five levels of warnings which FDA can require on a label. A black box warning indicates that a prescription drug can cause serious or life-threatening side-effects.

122. In October 2007, FDA approved labeling for Abilify indicating the drug for treatment of schizophrenia in adolescents 13 to 17 years of age.

123. In November 2007, FDA approved labeling for Abilify indicating it as an adjunctive treatment for major depressive disorder ("MDD") in adults. The phrase "adjunctive treatment" refers to the use of an additional medication to supplement an existing therapeutic regimen.

124. Also in November 2007, FDA modified Abilify's required "black box" label, advising that Abilify had been associated with "INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS and SUICIDALITY AND ANTIDEPRESSANT DRUGS." This warning provided:

- Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. ABILIFY is not approved for the treatment of patients with dementia-related psychosis.
- Children, adolescents, and young adults taking antidepressants for Major Depressive Disorder (MDD) and other psychiatric disorders are at increased risk of suicidal thinking and behavior.

125. In February 2008, FDA approved labeling for Abilify indicating it for treatment of acute manic and mixed episodes associated with Bipolar 1 Disorder in pediatric patients 10-17 years of age.

126. Also in 2008, the FDA required new safety information to be included in relation to the warning regarding increased mortality in elderly patients with dementia-related psychosis.

127. In November 2009, FDA approved labeling for Abilify indicating it for treatment of irritability associated with autistic disorder for pediatric patients ages 6-17 years.

128. Thus, from 2005 through October 2007, the only approved labeling for Abilify was for the treatment of schizophrenia and bi-polar disorder in adults. In

November 2007, an additional indication was received for adjunctive treatment of MDD in adults. The only approved indications for adolescent and pediatric patients were after October 2007, and were limited to the treatment of schizophrenia in adolescents; the treatment of Bipolar 1 Disorder in patients ages 10-17; and irritability associated with autistic disorder for patients ages 6-17.

VI. ALLEGATIONS OF FACT.

A. Corporate Policies and Practices.

129. In approximately 1999, Otsuka and BMS entered into an agreement to co-develop and co-promote sales of Abilify worldwide. BMS purchases the product from Otsuka, performs the finish manufacturing for sale, and is responsible for the invoicing of all third-party customers. BMS and Otsuka share in the revenue recognized by BMS for the net sales of Abilify, pursuant to contractually-recognized shares. For Abilify sold in the U.S., BMS recognizes more than 50% share of the net sales of Abilify.

130. As detailed below, Defendants BMS and Otsuka implemented a marketing strategy to improperly co-promote Abilify for off-label use.

131. Despite the fact that both Defendants entered into Corporate Integrity Agreements with the United States to resolve allegations regarding off-label promotion of Abilify from 2002 through 2005, Defendants blatantly continued their illegal marketing strategy.

132. Defendants formed sales teams to work together in their widespread targeting of providers to prescribe Abilify for off-label uses, including by targeting providers of child and adolescent patients, and geriatric care patients, and by marketing its use for diagnoses which are not medically-indicated by its label. In so doing,

Defendants directed their sales teams to continue to target doctors with whom the Corporate Integrity Agreements were designed to prohibit contact.

133. From 2005 to 2007, BMS marketed Abilify through the Residential Care Division (RCC). Abilify's only FDA-approved indication at that time was for bipolar disorder and schizophrenia in adults. In October 2007, in anticipation of the FDA-approved indication for major depressive disorder ("MDD") for adults, the RCC division was dissolved and was re-organized into the Neuroscience Division, which was divided into Office-Based Sales (OBS) and Account-Based Sales (ABS). In late 2007 and early 2008, respectively, Abilify received an indication for schizophrenia in adolescents 13 to 17 years of age, and the treatment of manic and mixed episodes for Bipolar 1 Disorder for pediatric patients ages 10-17.[1] In October 2009, almost two years later, the Neuroscience Division was again re-organized into OBS and Pediatric-Focused Sales (PFS).

134. During that time frame, Otsuka co-promoted Abilify, and assigned Otsuka counterparts tin each sales territory, though the Otsuka representatives marketed mainly to office-based providers, rather than institutional providers. The Otsuka counterparts participated in the BMS-run sales teams, and as explained further below, called on many targets shared with BMS sales representatives.

135. BMS generated call lists for sales teams, called "pods", led by BMS, which contained both BMS representatives and the Otsuka counterparts for that territory. BMS sales representatives worked with Otsuka counterparts, who regularly attended BMS sales strategy meetings, and received BMS instructions and promotion materials.

[1] In November 2009, Abilify received an additional indication for treatment of irritability associated with autistic disorder for pediatric patients ages 6-17 years.

The team members often shared weekly updates regarding their coverage area and targets with each other. BMS and Otsuka management also attended regular strategy meetings together, as well as attending quarterly and national sales meetings. Otsuka representatives, however, called not just on the targets in BMS sales plans, but also called on a range of other targets, without regard to the appropriateness of the target or the sales message.

136. In late 2009, when the BMS Neuroscience Division sales force was re-organized into OBS and PFS, the electronic system for sharing call plans and call notes, and tracking sales, was changed from "Call Max" to "Navigator" and became a shared system between BMS and Otsuka representatives. The representatives from BMS and Otsuka still participated in pods, but had shared access to call notes. When BMS Neuroscience was re-organized, many BMS sales representatives were terminated and hired by Otsuka.

137. Throughout the time frame, BMS and Otsuka sales representatives would be part of a "pod" for marketing to providers within a territory and would collaborate closely on shared targets. Targeted providers would then receive multiple calls from both BMS and Otsuka sales representatives, who in turn were required to call on the targets on their call lists a required number of times within a month.

138. Both sales forces were incentivized by a volume-based compensation system to call on providers and increase prescribing habits, without regard to appropriateness of the targets or the message. Up until 2009, BMS and Otsuka representatives were compensated according to the volume of prescriptions in their territories. After 2009, BMS sales representatives were compensated based on Sale

and Call Attainment scores ("SAS/CAS"), in which there were rated on their ability to meet the reach and frequency of calls on their call plans. Inability to meet the SAS/CAS affected not just compensation and bonus, but yearly reviews, and ultimately, continued employment.

139. By way of example, when Relator Ibanez was an RCC sales representative from 2005 to 2007, Otsuka representatives Jeff Schneider and Alex Fischer were assigned to the same territory. Mr. Schneider worked in the Dayton and northern Cincinnati, Ohio area, and Mr. Fisher worked in the Cincinnati, Ohio and northern Kentucky area. Prior to any child or adolescent-approved indications in October 2007, BMS and Otsuka sales teams made calls on child and adolescent psychiatrists. When Relator Ibanez became an ABS representative in late 2007, the same Otsuka representatives were assigned to overlapping territory. He continued to work with Mr. Schneider until January 2009, and with Mr. Fisher until July 2010. Relator Ibanez observed that both Mr. Schneider's and Mr. Fisher's call lists contained providers who treated patient classes for whom there were no approved indications. When Relator was in the Neuroscience Division, Relator Ibanez and Mr. Fisher received identical target lists which continued to include providers who treated unapproved patient classes.

140. Throughout his time at BMS, Relator Ibanez observed field-level sharing of data between BMS and Otsuka, as well as shared call plans, quarterly management strategy sessions and weekly meetings between representatives. He learned from his Regional Business Director, Steve Mahle, that Otsuka kept a strict eye over the BMS sales organization, to include the number of BMS representatives in the field, the

number of territories BMS targeted, and the number of calls made. Changes in the sales organization had to be approved by Otsuka, as Relator understood that BMS was required to keep to certain quotas in its sales coverage of Abilify.

141. By way of further example, Relator Derrick worked with two Otsuka representatives from 2005 to 2007. In 2006, Relator Derrick attended a state planning meeting for her manager that included both BMS and Otsuka management. Between March 2008 and October 2009, Otsuka sales representative Shauna Eginton attended at least ten joint sales presentations and luncheons scheduled by Relator Derrick. Ms. Eginton, a member of Relator Derrick's team, was regularly apprised of BMS sales efforts and provided her own updates in return. Ms. Eginton and other Otsuka counterparts (including, without limitation, Anna Mars), also shared in the logistics and planning of marketing programs. For example, Otsuka and BMS sales representatives took turns coordinating speaker lunch and dinner events, including sending out invitations that contained the names of both Otsuka and BMS sales members.

142. Relator Derrick observed that both Defendants were heavily involved in the planning of the marketing strategy. BMS and Otsuka sales representatives openly shared territory and target lists, with Otsuka representatives using BMS corporate-prepared call plans, Further, after the BMS Neuroscience Division reorganization in 2009, this sharing was more open, with Otsuka representatives using the same software (Navigator) to track and document sales efforts.

143. This joint off-label promotion of Abilify by Defendants caused the submission of false claims to government-insured healthcare programs in violation of federal and state False Claims Acts, as detailed below.

B. Illegal Off-Label Promotion: Residential Care Division.

144. In approximately June 2005, BMS reorganized its Long Term Care Division ("LTC") as "Residential Care" (called "RCC"). Between 2005 and October 2007, Abilify's only FDA-approved indication was for bipolar disorder and schizophrenia in adults. At that time, Relator Derrick was a Residential Care sales representative for Abilify in Arizona and Las Vegas, and Relator Ibanez was a Residential Care sales representative for Abilify in Ohio.

145. Notwithstanding the plain dictates of federal healthcare laws, BMS directed the Abilify sales force to target pediatric doctors to induce them to prescribe Abilify for children.

146. During this time frame, Relator Ibanez observed that BMS was directing the promotion of Abilify in child and adolescent psychiatric practices in the Cincinnati and Dayton, Ohio areas, including without limitation at the following locations:

a. Kettering Youth Services, Moraine, OH

b. St. Joseph Orphanage, Cincinnati, OH

c. Mercy Hospital Mt. Airy, Cincinnati, OH

d. Core Behavioral, Cincinnati, OH

e. Beechacres, Cincinnati, OH

f. South Community, Dayton, OH

g. MRDD facilities, Dayton and Huber Heights, OH

h. Children's Hospital Medical Center Hamilton Campus, Cincinnati, OH

i. Children's Hospital Medical Center Main Campus Outpatient, Cincinnati, OH

j.

k. CHILD FOCUS, Batavia, OH

l. Family Services, Covington, KY

m. NorthKey, all outpatient offices

n. Northkey Inpatient hospital, Covington, KY

o. Neuroscience and Behavioral Association

p. Northern KY Psychiatry Associates

q. Talbert House, Cincinnati, OH

r. Day-Mont Behavioral Health Care, Inc., Dayton, OH

s. Samaritan Behavioral Health, Dayton, OH

t. Mental Health Recovery Center, Dayton, OH

u. ATS Behavioral, Dayton, OH

v. Eastway, Dayton, OH

w. Mahajan Therapeutics, Dayton, OH

x. Recovery Center Inc., Xenia, OH

y. Integrated Youth Services, Dayton, OH

z. Focus Care, Dayton, OH

aa. Centerpoint Health, Cincinnati, OH

bb. Wright-Patterson Air Force Base

cc. Practice of Vincent Ziegler. M.D.

dd. Practice of Tangvald and Associates

ee. Practice of Bruce Snider, M.D.

ff. Practice of Arnold Shapiro, M.D.

gg. Practice of Michael McIntosh, M.D.

hh. Practice of Gary Balster, M.D.

ii. Practice of Constance Ange, M.D.

jj. Practice of Sunita Agarwal, M.D.

kk. Practice of Christina Waite, M.D.

ll. Practice of Christina Weston, M.D.

mm. Practice of Stephanie Riolo, M.D.

nn. Practice of Robert Simms, M.D.

oo. Practice of Michael Maloney, M.D.

pp. Practice of Mary Matias Akhtar, M.D.

qq. Practice of Dr. Marlene Schmidt, M.D.

147. Mr. Ibanez's call targets included frequent calls upon Wright Paterson Air Force Base, even though the target doctors at the base were child psychiatrists and there were not approved pediatric indications. By way of example, Mr. Ibanez made one such call on May 23, 2006.

148. Mr. Ibanez observed that the Otsuka representatives in his territory, Jeff Schneider and Alec Fisher, were also making inappropriate calls on child and adolescent providers. In addition to the inappropriate targets identified in BMS sales plans, Otsuka sales representatives called on a broad range of other providers. Relator Ibanez observed that Otsuka had even broader call lists than BMS; indeed, even in the infrequent case that a target was removed from the BMS database, that provider may still be called on by an Otsuka representative.

149. During this time frame, Relator Derrick's call targets in Arizona were primarily adult offices. Like Relator Ibanez, Ms. Derrick also worked with Otsuka

counterparts. During this time frame, she was directed to call on the Melmed Autism Clinic, which was headed by Dr. Raun Melmed, an international BMS speaker. Although the majority of the patients at Melmed were pediatric, she was told by her manager Scott Davis and her co-workers that she should leave samples with the clinic and that the two nurse practitioners who treated adult patients would sign for samples. These samples would be utilized by the entire office of developmental pediatricians.

150. Ms. Derrick is aware that her retail sales representative counterparts were not restricted in call targets, and had free reign over their call lists. In approximately January 2007, for example, one of Ms. Derrick's counterpart retail representatives, Ron Rowden, gave a lunch presentation to an inpatient pediatric facility in Tempe, Arizona. Ms. Derrick raised this issue to manager Jeanne Flaherty, who called Scott Davis, the retail representative's manager. She is aware of no repercussions for this inappropriate call, and this representative was promoted to the Oncology Division shortly thereafter.

151. In this time frame, and as identified in Section C.2 below regarding nursing home patients, Abilify sales representatives were also inappropriately marketing Abilify in nursing homes. In 2005 through 2007, Abilify was only indicated for schizophrenia and bipolar disorder for adults. Abilify sales representatives were directed to, notwithstanding the lack of schizophrenia and bipolar patients in that population, by marketing the symptoms of schizophrenia or bipolar patients that may be similar to those exhibited by elderly and/or demented patients.

C. <u>Illegal Off-Label Promotion of Abilify: Neuroscience Division.</u>

152. In October 2007, the national LTC/RCC sales force was dissolved and became the Neuroscience Division. It was divided into Account-Based Sales (ABS) and

Office-Based Sales (OBS). Relator Ibanez was assigned to ABS, which is comprised of Abilify sales to hospitals, children's hospitals, and nursing homes, and Relator Derrick was assigned to OBS, which is comprised of Abilify sales to office-based psychiatrists. Like in the LTC/RCC Division, BMS representatives had counterparts at Otsuka, who mainly called on office-based providers.

153. In November 2007, Abilify received a much-anticipated indication as an adjunctive treatment for major depressive disorder ("MDD") in adults. BMS began to aggressively promote Abilify for depression. Abilify also became indicated for treatment of schizophrenia in adolescents aged 13-17. Not long thereafter, in February 2008, the FDA approved an indication for Abilify for the treatment of manic and mixed episodes for Bipolar 1 Disorder for pediatric patients ages 10-17.

154. Both ABS and OBS representatives were permitted to detail all indications.

1. Pediatric Call Lists Post-2007 Indications.

155. Shortly after receiving the pediatric indication, the ABS field sales representatives received an "approved list" of child and adolescent psychiatrists for promotion of Abilify. The lists were based on an algorithm evaluating the physical age of pediatric patients treated by the psychiatrists, and were targeted to doctors treating children over 13 years of age.

156. This list caused a significant reaction in the sales force, who viewed it as a "drop list" of doctors because they lost many high-prescribing child and adolescent psychiatrists. In order to re-institute a doctor on his or her call list, the sales representative completed a physician survey delineating the age demographics of the

target's practice and establishing that the doctor did not treat patients less than 13 years of age.

157. Notably, these surveys were only conducted on selected doctors at the solicitation of the sales force, as described above. Such surveys were not comprehensively completed on all pediatric doctors.

158. Based on the number of pediatric doctors "dropped" from existing call lists, there were a significant number of pediatric doctors on BMS and Otsuka call lists prior to the receipt of a pediatric indication.

159. By way of example, in this time frame Relator Ibanez was the ABS representative in Dayton, OH and closely partnered with BMS representatives Jennifer Evans and Donald Conley, as well as Otsuka representative Jeff Schneider. In approximately February 2008, Ms. Evans scheduled a lunch at Kettering Youth Services, a child psychiatric hospital, in order to introduce Mr. Ibanez as the new representative taking over the hospital. Evans told Ibanez that the Kettering Youth Services contained the top Abilify prescribers, who were vital to the Dayton territory market share. Evans told Ibanez to keep up the Abilify Intramuscular Injectable (Abilify IM) usage momentum in the pediatric hospital (notwithstanding that it was only indicated for adults) because Dr. Sunita Agarwal at the facility already prescribed Abilify for agitated pediatric patients. Evans also introduced Mr. Ibanez to Cincinnati Children's Hospital Outpatient Clinic. She made clear to Relator Ibanez that the pediatric psychiatry hospitals are market share drivers for the OBS team and that they have been calling on them since the launch of Abilify, notwithstanding that there was pediatric indication prior to late 2007.

160. Ms. Evans also told Mr. Ibanez that they get credit not just for every discharged patient on Abilify, but for any new prescriptions written by the same doctor in his or her private practice. Because the sales representatives from both companies were compensated based on the prescribing volume in their territories, this created significant pressure to call on a wide range of doctors, including inappropriate targets.

161. During this period when the call lists were adjusted by BMS, Otsuka representatives were calling on targets without regard to whether the doctors were re-identified on call lists or surveyed for appropriateness.

162. After the initial call list was issued, there was little additional effort to differentiate the targets for adult and pediatric indications.

163. Relator Ibanez observed that a significant number of pediatric doctors treating patients under the age of 13 remained on call lists and that representatives with MDD promotional material for adults were promoting Abilify to pediatric targets on their call lists.

164. Relator Derrick received a Direct Marketing Expense ("DME") Plan for Phoenix North 2008. For the first quarter 2008, the instruction was to "focus on Ped." It included five scheduled events for BMS speaker Dr. Roth at the Melmed Center. Melmed treats pediatric patients with autism, which was not at that time an approved indication.

165. In 2008, Relator Ibanez received a request from the Pediatric Intensive Care Unit (PICU) at Children's Hospital Dayton for a product in-service on the use of Abilify IM for pediatric patients in the ICU (and, specifically, to inquire about its use for chemical sedation). Relator Ibanez was concerned by the request since the use was off-

label, and contacted his District Manager Dion Smith for guidance. Mr. Smith approved the program and a lunch program was performed with paid BMS speaker, Dr. Jerome Schulte.

166. Lunches were regularly scheduled as a way to target inappropriate providers. For example, a lunch was scheduled on September 17, 2009 at the Melmed Center, with the topic "Treating Pediatric & Adolescent Patients with Bi-Polar, Manic, Mixed or Schizophrenia" though the audience was doctors with autism patients.

167. By way of further example, on October 29, 2009, BMS hosted a lunch at Pappadeaux's where John T. Hardy spoke on "MDD: Adjunctive Abilify for Adults Plus Review of Safety Data" to a group of providers, including Drs. Ann Guthery and Edwin Perez who treat exclusively pediatric patients. Also in attendance was Otsuka sales representative Shauna Egington.

168. In April, 2009, Relator Derrick made a request to her manager Scott Davis that region or national teleconferences be set up for child physiatrists because she and the rest of the sales team lacked proper marketing materials for providers specializing in child psychiatric care. Though they were calling on child and adolescent providers, they only had one visual aid to use. Ms. Derrick summarized her request in an email update to her colleagues Denise Bueno, Anna Mars, and Shauna Eginton, of Otsuka.

169. The lack of separation in message is illustrated by Relator Derrick's Field Coaching summary dated March 12, 2009. On that day, she was observed and rated by her manager, Scott Davis. In a section regarding "Product Messaging Observations" she was rated based on how well she delivered particular product messages, but her rating was only related to MDD messaging. This was very typical of the directions she

received in the Field Coaching Summaries—they emphasized MDD messages but never focused on, or provided any direction regarding, whether there was appropriately-tailored messaging for child psychiatric care. Her April 6, 2010 Field Coaching Summary, by way of another example, listed the same MDD messages.

2. Nursing Home Off-Label Promotion.

170. During a 2008 regional POA meeting in Columbus, Ohio, Relator Ibanez was involved in an ABS Breakout training session regarding "selling in the Nursing Home Environment." Terry McCurren, former BMS District Business Manager, led the session. He told the ABS team that it is not illegal to discuss or promote dementia if the doctor asks an unsolicited question. McCurren told the team that Abilify is not contraindicated for dementia, and authorized ABS representatives to discuss the dementia data list in the package insert.

171. Throughout 2008 and 2009, Relator was required to target nursing home medical directors and consultant psychiatrists, including without limitation Drs. Hernandez, McConnell, Scheidler, and Shackson. He was required to submit information regarding his contacts with the physicians to his District Business Manager ("DBM"), Dion Smith. Relator would report notes of the doctor's concern and his planned focus for the following visit. Mr. Smith used this information to prepare for when he would join his sales representatives on calls. By way of example, the call notes on Dr. Hernandez on May 27, 2008 reflected "scheduled MDD inservice Glendale Place Care Center;" on June 18, 2008 stated "having great success with A for MDD patients in LTC;" and on January 16, 2009 "now rxing for MDD Nursing Homes."

172. Mr. Ibanez was provided a list of target skilled nursing facilities that contained 42 facilities with an aggregate 5,218 beds.

173. During promotional sessions, doctors expressed their objections to the use of the antipsychotic Abilify for their patients because they are typically demented, and not depressed.

174. When asked to do so for a speaking engagement, Dr. Neil Richtand, University of Cincinnati Department of Psychiatry, refused to present the BMS slide deck for "Patients in Nursing Homes with MDD" and the sales aid "Nursing Home Core Visual Age." He stated that the use of antipsychotic in the geriatric population is not valid, safe or ethical, and that there is no current data to support the use of Abilify or other agents in elderly patients. Dr. Richtand specifically questioned that Abilify is being promoted to address behavior and symptoms, and not disease.

175. DBM Dion Smith told Relator Ibanez that Abilify is not contraindicated for dementia, citing positive trials with demented patients.

176. In 2008 and 2009, the ABS sales force was encouraged to use the sales aid, "Adjunctive Use of Abilify for MDD," in nursing homes. The ABS sales force also used a sales aid, "Nursing Home Core Visual Age," showing picture of a 63 year-old nursing patient named Mary and stating "more than one third of nursing home residents have a diagnosis of MDD." The front page of the sales aid prominently lists the symptoms "Depressed mood, Loss of energy, Loss of interest, Feelings of worthlessness, Sleeping too much."

177. ABS representatives were instructed to "paint the picture" of 63-year old Mary residing in a nursing home. They were trained to identify one symptom of the

depression used in the visual aid, which may also be in common with early onset dementia.

178. The sale force was directed to lead promotional calls with symptoms and treatment of symptoms, instead of diagnoses. They focused heavily on cognitive difficulties, aggressiveness, lethargy, and irritability. The data in the BMS materials addressed:

Apparent Sadness	Concentration Difficulties
Reported Sadness	Lassitude
Inner Tension	Inability to feel
Reduced Sleep	Pessimistic Thoughts
Reduced Appetite	Suicidal Thoughts

179. For example, a May 2008 ABS Teleconference directed the Abilify sales team to market to "state institutions" for "patient types identified with MDD" by focusing on the symptom presentation of "concentration difficulties," "pessimistic thoughts" and "suicidal thoughts," citing that "[u]sually Geriatric population on multiple medication, 20 years or more in the facility."

180. In an "Assisted Facility Guide," the Abilify sales force is directed to "concentrate on how to identify the [symptoms] of depression."

181. Mr. Smith frequently stated to doctors, without data and contrary to the black box warning, that Abilify reduces the incidence of suicide.

182. Sales representatives were instructed to sell the symptoms to geriatric doctors, notwithstanding that there was no data to support the safety, efficacy, or tolerability of Abilify in the geriatric population.

183. For example, Relator Ibanez was encouraged by his manager to obtain prescriptions of Abilify for "lethargic" nursing home patients. Relator and other salesmen would provide pre-call planning notes to his manager regarding calls to long-term care doctors. These notes often reflect the goal, as directed by his manager, of obtaining prescriptions of Abilify for "lethargic" nursing home patients. In one set of those notes, for example, sales representative Albert ("Al") Zennie documented a call with Dr. Scheidler in July 2009 that indicated he would agree to prescribe low-dose Abilify for lethargic patients. Also, call notes on Dr. Hernandez at the Lodge Care Center in January 2009 reflect he was "committed to prescribe for lethargic patient."

184. This was equally true prior to receiving the MDD indication in late 2007. Prior to that time frame, in 2005 through 2007, Abilify was only indicated for schizophrenia and bipolar disorder for adults. Abilify sales representatives were directed to market Abilify in nursing homes, notwithstanding the lack of schizophrenia and bipolar patients in that population, by marketing the symptoms of schizophrenia or bipolar patients that may be similar to those exhibited by elderly and/or demented patients.

185. Because schizophrenia and bipolar patients represent such a small fraction of the patients in the nursing home population, marketing Abilify in nursing homes is like marketing to a "ghost population." By marketing Abilify to treat symptoms that may exist in the elderly, Defendants intended to induce the prescribing of Abilify off-label to elderly patients, without regard to diagnoses and without regard to the black box warnings.

186. While Relator was assigned to the RCC division (pre-2007), he was also directed to market to Alois Alzheimer Center, a facility treating Alzheimer and dementia patients. He questioned his DBM at that time, Ellen Weaver-Bailey, regarding the off-label implications of presenting Abilify in that facility, and in particular raised his concerns about the black-box warning regarding dementia patients. She directed Relator to proceed and to have Dr. Bill Kasper, BMS Medical Science Liaison, perform the in-service. Based on that instruction, Relator Ibanez organized a catered lunch for the Alois staff. Dr. Kasper presented the Abilify Schizophrenia & Bipolar Disorder speaker's slide deck, and received numerous questions regarding the similarity of symptoms between dementia and schizophrenia and bipolar disorder. Consistent with the BMS corporate message, Dr. Kasper discussed with the staff that the efficacy of symptom control in the BMS studies would indeed help the center control their dementia patients with similar symptoms.

3. Illegal Promotional Schemes Not Limited to Setting.

187. Abilify sales representatives were instructed to use the illegal promotional schemes described above in all settings.

188. As described above, Abilify sales representatives were directed by Defendants to sell the symptoms to all providers, including child and adolescent providers.

189. For example, Relator Ibanez was encouraged by his manager Dion Smith to promote the off-label use of Abilify by associating symptoms for other disorders with similar symptoms for schizophrenia, such as behavior associated with oppositional defiant disorder (ODD) and other conduct disorders.

190. By way of further example, Ms. Derrick attended a regional teleconference, at which the attendees were encouraged to tie Abilify to improved sleep habits.

191. By way of further example, sales representatives were trained to market Abilify as an activator – to persuade the doctor that it would make the geriatric patient "more interactive," or the adult patient more functioning or energetic.

192. Abilify sales representatives were trained to paint the picture of a symptomatic patient, rather than focus on the actual diagnoses.

193. In that way, Abilify sales representatives would market the use of Abilify for a single symptom rather than for on-label diagnoses.

194. Abilify sales representatives were trained to get the provider's buy-on to Abilify for his or her patient, through marketing of symptoms, and then discuss how to move Abilify up the "line of therapy."

195. Abilify sales representatives were trained with many ways to accommodate a provider's concerns with the use of Abilify, including through a "go low, go slow" message of step therapy. Abilify sales representatives were directed to accommodate any concerns about side effects (such as, for example, akathisia) by reducing the dosage or augmenting with other medication. Abilify sales representatives were trained to suggest that providers split the tablets to reduce the dosage.

196. Abilify sales representatives were trained not to detail the long-term side effects and focus only on short term effects, when asked. For example, Relator Ibanez was trained to describe Abilify as weight-neutral based on short-term data, notwithstanding that long-term data showed weight gain for children.

197. Abilify sales representatives were trained to market these messages to all "key influencers" on prescription writing, including without limitation LTC nurses, Directors of Nursing, nurses and nurse practitioners in physicians' offices, and pharmacy directors.

198. As reflected in these schemes, Abilify sales representatives were not limited to approved on-label messaging and, instead were directed to deliver a wide range of illegal promotional information to providers and "key influencers" in order to induce the prescribing of Abilify.

199. Moreover, as described further below, Abilify sales representatives were incentivized by their volume-based compensation system to call on providers and increase prescribing habits, without regard to appropriateness of the targets or the message.

200. Relators observed that sales representatives were pressured both by BMS and Otsuka to engage in these schemes.

4. <u>October 2009 Re-Organization.</u>

201. In October 2009, almost two years after receiving the new indications (MDD adult and schizophrenia/bipolar for adolescents), BMS re-organizes the Neuroscience sales force into OBS and Pediatric-Focused Sales ("PFS"). OBS representatives, like Relator Derrick, are directed to detail the MDD message only, while the former ABS representatives, now PFS, like Relator Ibanez, are supposed to detail pediatric messages.

202. Under this structure, BMS and Otsuka OBS representatives were to only have MDD promotional materials, for the promotion of MDD only. Unlike the time frame

prior to this restructuring, representatives are separately trained on MDD and PFS materials. Thus, after the restructuring, the OBS representatives did not have the material to detail the pediatric message.

203. On November 17, 2009, Jennifer Derrick received a memorandum from her then-manager, Scott Davis. In the memo, Davis states "Sales message: "MDD all the time except in the Magellan SMI Clinics where it is adult indications only and you are never to detail adolescent schizophrenia or Bi-Polar from this point on!"

204. This "MDD all the time" for OBS sales representatives was a corporately-directed message delivered to all Abilify sales representatives. For example, a March 17, 2010 memorandum to the national sales force made clear that "OBS (Office-Based Specialists) will deliver Adult Adjunctive MDD calls to their targets." The national memorandum directed that OBS reps were not to plan pediatric promotional programs "based on the business decision to focus on Adult Adjunctive MDD as the #1 opportunity."

205. Notwithstanding this message, Relator Derrick observed that child and adolescent providers remained on the OBS call lists. Because sales representatives are required to call on all targets on their call lists in order to meet their quota, Relator Derrick became increasingly pressured to call on child and adolescent provider targets. She became very concerned with the continued assignment of these targets, and the inappropriate promotion necessitated by these assignments.

206. For instance, Relator Derrick's Call Plan for the 3rd and 4th Quarters of 2009 included a directive to put resources and time toward a specific group of targets (samples, DMEs, coupons—office contact at least once a week). Five of the six offices

to which Relator was assigned were child psychiatrists: Chundu, Tan-Fermo, Djavardi, Perez and Prince. In addition, her counterparts at Otsuka, Shauna Egington and Anna Mars, were also assigned child psychiatrists. Ms. Egington had seven child psychiatrists on her list and Ms. Mars had five. The Call Plan directed BMS and Otsuka reps to make calls at least once a week on targets.

207. This directive is driven home by the demand that representatives call on high quintile providers in order to meet their sales goals. High Quintiles refers to high atypical antipsychotic prescribers. All doctors are divided into Quintiles based on the number of prescriptions they write for atypical antipsychotics, with Quintile 5 being the highest ranking.

208. In both 2008 and 2010, for example, BMS management (Scott Davis) instructed sales representatives to "[f]ocus on getting 60% Quintile 5&4 and 40% of Quintiles 3, 2, &1 to DME Program" and that planning was "critical."

209. Because most of Q5 and Q4 providers are pediatric, the directive from the Davis Memo requires sales representatives to deliver an MDD message on child and adolescent providers.

210. In order to meet their goals, OBS reps are forced to continue to call on child and adolescent providers because there are not enough adult-only high quintile providers to meet their assigned quotas (referred to as "SAS" and "CAS") and justify 60 percent of the lunch and DME budget. The ability to hit these assigned goals affects bonus compensation and reviews, and in turn affects whether they will stay employed. Thus, in order to meet the assigned quintiles there is enormous pressure for OBS

representatives with MDD messaging to continue to call on child and adolescent providers.

211. By way of example, a Physician Level Report received by Ms. Derrick in November 2009 identifies the quintile rating of Abilify prescribers. Of these, approximately 15 of the 33 Q5s and Q4s are child or adolescent providers.

212. During this time frame, Relator Ibanez similarly observed that OBS counterparts in Ohio were calling on PFS targets with the MDD message, and that these targets were high quintile providers.

213. In early November 2009, BMS held regional meetings. Relator Ibanez attended a regional meeting in Orlando, Florida, while Relator Derrick attended a meeting in La Jolla, California. At those meetings, BMS sales representatives are directed by BMS to review their call lists in the software system, Call Max, to finalize their call lists to those targets relevant to their respective message.

214. The deadline for sales representatives to "clean up" the lists was November 7, 2009 and then a second "snap-shot" was to be taken December 31, 2009. After the changes were entered into the system, data was being switched to a new system, Navigator. The Navigator system was being introduced at the National Sales Meeting in Dallas in January 2010 and all Abilify sales representatives, including Otsuka representatives, were to use Navigator after that meeting.

215. At the breakout sessions for her district in La Jolla, Relator Derrick openly voiced her concerns regarding the inappropriate targets on her list and her concerns with giving MDD-only presentations to child and adolescent providers. Additionally, she expressed her concerns about the compliance issues relating to how they were directed

to conduct inappropriate calls. In discussions on this issue that ensued in November and December, she was assured that the lists would be "cleaned up."

216. Relator Ibanez expressed similar concerns regarding his OBS counterparts calling on PFS targets. In a December 28, 2009 email to the helpline, Mr. Ibanez identified questions he had with the widespread practice of BMS and Otsuka OBS representatives calling on PFS targets. He specifically raised questions with the correct roles of OBS and PFS representatives. He reported that: "[t]he issue being faced in all areas of the country is that BMS and Otsuka OBS are still calling on PED-ONLY Psychiatrist[s]."

217. In addition, in his district breakout with the District Manager at the January 2010 National Sales Meeting in Dallas, Relator Ibanez presented a Power Point on the "Opportunities" and "Challenges" for PFS in his Cincinnati territory (a typical update given by all the representatives at that meeting) which specifically identified that a challenge was "OBS Calling PFS Targets." His presentation posed the question: "Need to Define --What is an OBS target? --What is an ABS Target? Compliance or Non-Compliance." His questions were not addressed.

218. Relator Derrick and many other representatives submitted recommended changes to their call lists within the deadlines provided, but such recommendations were ignored. The April 2010 Call List was issued with much of the original list in effect.

219. For example, in April 2010, Otsuka representative Alec Fisher had the following high quintile child and adolescent providers on his "bucket list:" Drs. Joseph Cresci, James Eppley, Michael McIntosh, Wayne Harrison, Hugh Pettigrew, Rodney Vivian, Arnold Shapiro.

220. Even had changes been made, this type of subjective "clean-up" by the sales team, who were incentivized by their compensation plans not to remove targets, was not only two years after new indications but wholly failed to meet Defendants' obligations under their CIAs. More to the point, it resulted in lax oversight and continued off-label promotion of Abilify by BMS and Otsuka sales representatives.

221. Both Relators observed that, on certain occasions in prior years, efforts to review or narrow target lists (for example, in response to the black box warning) were done by the comprehensive completion of surveys of doctors and the types of patients treatments. No surveys were conducted in conjunction with the call lists developed to promote the adult and narrow pediatric indications obtained in 2007 and 2008. No comprehensive surveys were conducted in conjunction with the call lists developed to promote the adult and narrow pediatric indications, or in conjunction with this 2009-2010 ostensible effort to remove inappropriate targets from the lists.

222. On March 10, 2011, Scott Davis presented his 2010 District plan to Johanna Mercer, the head of Sales. Titled "#1 Key Opportunity/Initiatives – Selling Like an Antibiotic Rep," Davis outlines opportunities and initiatives for the PFS and Child/Adolescent Indications. This document reflects that there are 86 PFS-only psychiatrists in Arizona and that these doctors require weekly calls, but there are only 2 PFS representatives in the Phoenix, Arizona Neuroscience district of at BMS. It is not feasible for two PFS representatives to make weekly calls on all these doctors and, in fact, Relator Derrick is aware that Jack Briggs, one of the Arizona PFS representatives, is assigned a call list comprised solely of only a few of the PFS-only doctors. Many of the doctors on his list appear on the OBS call lists, and are shared targets.

223. Of note, this presentation also directs representatives to utilize only "high value" speakers (such as Drs. Rabin, Hardy, Fleming, Escolona) and to "communicate with Otsuka Reps on these specific targets (Q5, Q4, & Q3) weekly with specific actions."

224. In April 2010, BMS sales representatives, including Relators, received a voicemail blast from BMS Regional Business Director Steve Mahle stating that they were going to remove 1300 doctors from the OBS list. In April, the April-June 2010 Target List was issued. This Target List still contained many PFS-only doctors on the OBS call lists.

225. The following PFS doctors in Arizona are examples of those pediatric targets which were identified on OBS call lists in 2009, and not removed as part of any prior review:

	Name	**Quintile**
1	Letty Tan-Fermo	Q5
2	Leticia Jacinto	Q5
3	Derrick Hines	Q4
4	Leslie Kaminski	Q4
5	Benet Press	Q4
6	Nicholas Farrey	Q2
7	Judith Outten	Q4
8	Houshang Semino	Q4
9	Timothy Miller	Q4
10	Ann Guthery	Q4
11	Mary Nowlin	Q3
12	Elias Ruioba	Q3
13	Mark Harp	Q3
14	Sharon Paul	Q2
15	Vidnod Patel	Q5
16	Edwin Perez Vega	Q4

226. The following PFS doctors in Ohio are examples of pediatric targets identified on OBS call lists in 2009, and not removed as part of any prior review:

	Name	**Quintile**
1	George Broderick	Q2
2	Elizabeth Cottingham	Q3
3	Joseph Cresci	Q5
4	Melissa Delbello	Q2
5	Sergio Delgado	Q2
6	Carol Engel	Q3
7	James Eppley	Q5
8	David Franz	Q3
9	Elliott Friedeman	Q5
11	Richard Honig	Q2
12	Jennifer Johnson	Q3
13	Mark Johnson	
14	Marcia Kaplan	Q3
15	Velissarius Karacostas	Q2
16	Monica Kennedy	Q3
17	Robert Kowatch	Q3
18	Michael McIntosh	Q4
19	Sarah Morrison	Q2

20	Jayasree Nandagopal	Q2
21	Daniel Nelson	Q3
22	Erik Nelson	Q2
23	Jayanthi Peters	Q2
24	Hugh Pettigrew	Q4
25	Erik Powell	
26	Marlene Schmidt	Q3
27	Roslyn Seligman	
28	Arnold Shapiro	Q3
29	Janice Singerman	Q2
30	Robert Sorscher	Q3
31	Michael Sorter	Q3
32	Jeffrey Strawn	
33	Daniel Vogel	Q3
34	Sharon Wynn	Q2

227. The following PFS doctors in Arizona are examples of pediatric targets still identified on OBS call lists in 2010, and not removed as part of any prior review:

	Name	**Quintile**
1	Leslie Kaminski	Q4
2	Benet Press	Q4
3	Nicholas Farrey	Q2
4	Houshang Semino	Q4
5	Mary Nowlin	Q3

6	Elias Ruioba	Q3
7	Mark Harp	Q3
8	Sharon Paul	Q2

228. The following PFS doctors in Ohio are examples of pediatric targets still identified on OBS call lists in 2010, and not removed as part of any prior review:

	Name	**Quintile**
1	George Broderick	Q2
2	Elizabeth Cottingham	Q3
3	Joseph Cresci	Q5
4	Melissa Delbello	Q2
5	Sergio Delgado	Q2
6	Carol Engel	Q3
7	James Eppley	Q5
8	David Franz	Q3
9	Elliott Friedeman	Q5
10	Larry Graham	
11	Richard Honig	Q2
12	Jennifer Johnson	Q3
13	Mark Johnson	
14	Marcia Kaplan	Q3
15	Velissarius Karacostas	Q2
16	Monica Kennedy	Q3
17	Robert Kowatch	Q3
18	Michael Maolney	
19	Michael McIntosh	Q4
20	Sarah Morrison	Q2
21	Jayasree Nandagopal	Q2
22	Daniel Nelson	Q3
23	Erik Nelson	Q2
24	Jayanthi Peters	Q2
25	Hugh Pettigrew	Q4
26	Erik Powell	
27	Marlene Schmidt	Q3
28	Roslyn Seligman	
29	Arnold Shapiro	Q3
30	Janice Singerman	Q2
31	Wiley Smith	
32	Sorscher, Robert	Q3
33	Sorter, Michael	Q3

34	Jeffrey Strawn	
35	Vogel, Daniel	Q3
36	Wynn, Sharon	Q2

229. The call notes reflect that these doctors are easily identified as child and adolescent providers by the sales team, but are not removed from call lists on multiple occasions over time. For example, on April 15, 2008, call notes reflect a sales representative calling on Dr. Jayasree Nandagopal and noting, "MDD indication/primarily dealing with child pop so applicability limited – not very responsive person – get to know better…" Yet, this same doctor continues to appear in the OBS call notes in June 2010.

230. By way of other representative examples: The call note for Dr. Jayasree Nandagopal on 4/19/08, states that "Patient pop (population) almost exclusively adol[escent]…" but this doctor continues to appear on the OBS call list through 2010.

231. In early April 2010, Relator Ibanez observed a lunch in-service being provided by an OBS representative. The representative was discussing adult depression with the doctor, Sharon Wynn. When Dr. Wynn told the representative that she does not see adult patients, he said "that's ok; I am talking about patients with depression, not adults in general."

232. Relator Derrick observed that BMS routinely invited child and adolescent doctors to lunches and speaker programs promoting the use of Abilify for depression. By way of example, she recalls an MDD speaker program provided at a dinner meeting for the Arizona Child Psychiatry Association in 2008 with approximately 25-30 child psychiatrists in attendance. Relator Derrick identifies "iplan rosters" as one of the documents that would reflect attendees at these programs.

233. On or around April 13, 2010, Relator Ibanez was invited to a meeting with BMS District Manager Keith Watters, BMS OBS representative Marty Hensley, and Otsuka representatives Alec Fisher and Cary Harris. In the course of the meeting, Watters asked each representative to identify and discuss their top prescribers. Dr. Joseph Cresci, child and adolescent psychiatrist, was identified by Hensley and Fisher as their top prescriber for Abilify. Dr. Cresci works at Beech Acres, a pediatric care organization. He does not treat adults. Hensley and Fisher went to say that Cresci's Abilify numbers are dropping and that they need to regain his trust. Harris then reported that he was working on a free trip for Dr. Cresci to the Kentucky Horse Park.

234. At that same meeting, another doctor identified as declining in Abilify prescriptions was Dr. Eliott Friedeman. Hensley told the meeting members that he spoke with Friedeman about picking his favorite restaurant in order to entertain the doctor, and was considering the creation of a speaker program to offer to Friedeman.

235. Hensley stated to Relator Ibanez that "the message and type of doctor is not important." Rather, "it is about selling Abilify not matter what!" Hensley also stated that seeing at least one adult patient is sufficient to make a doctor a valid target. Watters also added: "Don't you want OBS helping you in your accounts?" Watters made clear that "depression sales will make [BMS] number one; and that "doctors who augment will be targeted regardless of specialty."

236. At these meetings, neurologists were also identified as targets for the promotion of Abilify, notwithstanding that neurologists do not generally treat depression.

237. BMS's supposed efforts to refine the call lists were not just belated, but did not in fact remove child and adolescent targets from OBS or adult-only call lists, and as a result continued to direct the off-label promotion of Abilify.

238. This practice is still ongoing.

239. Recently, BMS district managers had sales call planning sessions (called "AIMS/BET" sessions) with their respective district direct reports. Al Zennie told BMS PFS sales representative Sally Maynard that, during his planning session with District Manager Keith Watters, the company had assigned off-label MDD calls on child/adolescent psychiatrists. Mr. Watters and Mr. Zennie changed the calls to child-approved indications and submitted a final call plan for Regional Office Approval. The changes were denied by Regional Manager, Michelle Calope. The same thing happened to Ms. Maynard and her call plan. Ms. Calope denied the changes recommended by Ms. Maynard and her manager, Steve Rosi. Ms. Calope changed the plan to the original MDD message. Ms. Calope stated to her region that no changes will be approved and they must adhere to the company-directed messaging. As Ms. Maynard put it, the message was, "If the company says MDD, that means MDD calls. Physician specialty will not be an excuse!" Ms. Calope also stated that the company uses ICD-9 diagnosis codes to determine what type of message the doctor should receive. Hence, if a psychiatrist treats a high amount of depression patients, then they will receive a depression call without regard to whether they treat adult or child patients. Ms. Calope also reinforced that each sales representative will maintain an 80% score on adherence to the call plan.

D. Illegal Inducements: BMS Speakers and Other Inducements.

240. During their tenure, Relators observed Abilify sales representatives inviting and/or creating paid programs, including speaking engagements and lunches, to induce high prescribers and their "key influencers" to continue to write Abilify prescriptions.

241. For example, Relator Ibanez has reported to BMS Compliance representatives that BMS-paid speaker and high-prescriber, Dr. Amita Patel of Dayton, Ohio, promotes Abilify use for patients with pseudo-dementia and aggressive behavior. She states that Abilify is neuro-protective in patients with dementia or depression, because dementia and depression have similar symptoms. Dr. Patel made clear that she would prescribe more based on the number of speaker programs she was awarded. BMS engaged Dr. Patel for at least three speaking programs, on June 25, 2008, February 12, 2009, and December 10, 2009.

242. Relator Ibanez has also reported to BMS Compliance representatives that the BMS sales representatives are permitted to nominate and influence the retention or termination of speakers in order to induce the prescribing of Abilify.

243. Relator Ibanez also reported to BMS compliance representatives that BMS sales representatives Donald Conley and Jennifer Evans asked DBM Dion Smith if he could get Dr. Mahmood Rahman added to district speakers list notwithstanding that the district was at its maximum allowable number of speakers. Smith called Regional Assistant Manager of Regional Operations, Keith Watters, and got Rahman added into district's speakers' pool based on Conley's and Evan's report that Rahman is the number one atypical market class prescriber in their territory and that Rahman

mentioned that he wanted the title of speaker on his CV. Conley reported that a speaker title on Rahman's CV would result in more Abilify prescriptions.

244. Conversely, another speaker, Dr. Randy Sansone of Miamisburg, Ohio, was dropped by Smith because he was not writing enough prescriptions. Relator Ibanez was directed by his manager Smith to clearly communicate to Dr. Sansone that BMS would not keep him as speaker if he did not change his prescription patterns. Relator reported these concerns to Human Resources.

245. Likewise, another BMS speaker, Dr. Michael Chan in Columbus, Ohio, was abruptly terminated as a speaker in 2008 by DBM Steve Rosi. Rosi stated to his district that Dr. Chan was not writing enough Abilify to warrant a contract and that there were more worthy doctors who should be rewarded with a speaker's contract because they were writing higher volumes of Abilify.

246. By way of another example, BMS-paid speaker Dr. Geraldine Wu of Cincinnati, Ohio, is retained as a speaker for her prescribing volume. BMS representatives Marty Hensley and Karina Fischer reported to the district that Dr. Wu was retained because she is that territory's "number one writer of Abilify and atypical antipsychotics." The representatives made clear that BMS would lose market share if she were dropped as a speaker because she would retaliate by not writing Abilify.

247. During Relators' tenure at BMS, BMS did not follow its own protocols for nominating, recommending, or appointing speakers.

248. Defendants offered doctors and "key infuencers" incentives as an inducement to prescribe Abilify, including paid speaking engagements, paid lunches, free samples, and other incentives.

249. Defendants' conduct violated the Anti-Kickback Statute and known conditions of payment in government healthcare programs. Claims resulting from these violations are false claims.

E. Knowing Conduct Resulting in False Claims to Government Healthcare Programs.

250. Defendants are aware that off-label uses of Abilify are not covered by Medicaid, Medicare, or other government healthcare programs and that claims for payment for such uses were not covered and payable by any of these programs.

251. Defendants are aware that claims resulting from violations of the AKS are not covered by Medicaid, Medicare, or other government healthcare programs and that claims for payment for such uses were not covered and payable by any of these programs.

252. Defendants are aware that the natural and probable consequence of their promotion of off-label uses of Abilify is that health care providers submit claims for payment to government payors for an off-label and noncovered and nonpayable use.

253. Defendants are aware that the natural and probable consequence of their offer and payment of illegal incentives to providers is that health care providers submit claims for payment to government payors for more prescriptions of Abilify.

254. Under their Corporate Integrity Agreements with the United States, and the dictates of federal healthcare laws, Defendants are required comply with the FDCA and the AKS.

255. Specifically, Defendants are required to review their call plans, survey their detailing materials, and ensure that Abilify representatives are not illegally

promoting it for off-label uses. In addition to their ongoing obligations under federal law, Defendants are required to annually certify that its activities are compliant.

256. Yet, Defendants did not diligently identify and remove inappropriate targets from their call lists, and instead directed its sales force to induce off-label prescriptions, including by inappropriately targeting child and adolescent providers and long term care facilities, and by inducing providers to prescribe based on isolated symptoms rather than medically-indicated diagnoses.

257. Thus, rather than ensure that their sales activities were compliant, Defendants incentivized their Abilify sales force to illegally promote Abilify. Compensation, bonus, performance reviews, and, ultimately, continued employment was directly tied to attainment of calls of their call lists, including required calls on inappropriate targets. Moreover, as reflected in sales force communications and other training materials, Defendants directed their sales force to market depression on all targets, without regard to appropriateness of the provider's patients, as "[a]djunctive MDD in adults remains the largest opportunity for the brand moving forward."

258. Defendants did everything they could to induce increased sales, including by continuing to offer illegal incentives in violation of the AKS.

259. Defendants knew their actions resulted in false claims to government healthcare programs. Defendants were well-aware that the targeted physicians' patients were government healthcare program beneficiaries, and they strategized their illegal marketing schemes to target the highest prescribers. Defendants' documents reflect that they well knew (and indeed tracked) that government healthcare programs represented the most significant payor of Abilify. Indeed, Defendants' documents show

that Defendants were aware that Medicaid was the primary payor for child and adolescent facilities, and that Medicare Part A and Medicaid Part D was the primary payor in long term care facilities (in one year, at least 75% of total beneficiaries nationally). In one document where the Abilify sales team discusses an approach to a child-adolescent home, it states "majority of child adolescent homes is Medicaid…Usually very easy to assume that patients are Medicaid patients."

260. Defendants track the prescribing levels of all its target physicians, and track the government healthcare reimbursement breakdown of its target audiences for marketing of MDD use, to include child, adolescent, and geriatric providers, both in office and institution settings.

261. In the years 2005 through 2011, Abilify's total reimbursement from Medicaid and non-Medicaid programs was more than $7 billion. The Medicaid-reimbursed portion of that number is almost $6 billion.

262. Notwithstanding knowledge of the material conditions of payment of Abilify claims and their ongoing obligations under existing CIA's, Defendants engaged in a corporate practice to induce the sales of Abilify to government healthcare programs through illegal incentives and illegal promotion of off-label uses.

263. On information and belief, this conduct is occurring nationwide and has been occurring since 2005.

264. Defendants are aware that their illegal incentives and illegal promotion of off-label uses did in fact result in claims to government payors. Defendants are aware that their incentive and promotion activities are a substantial factor in producing the claims.

265. False claims to government programs are the direct and proximate result of Defendants' illegal schemes. Defendants knowingly caused the submission of these claims.

266. Moreover, these continued schemes have resulted overpayments by government healthcare programs. Notwithstanding the terms of their CIAs or their obligations to report overpayments, Defendants have illegally retained these overpayments and continued their illegal conduct.

F. Retaliatory and Wrongful Termination of Relators.

1. Wrongful Termination of Joseph Ibanez.

267. On or about 2008, Relator Ibanez began raising compliance issues with his employer, objecting to inappropriate detailing and inappropriate call targets for the promotion of Abilify.

268. On or around December of 2009, for example, Relator Ibanez emailed the BMS legal department regarding a compliance concern from a paid BMS speaker, Dr. Neil Richtand at the University of Cincinnati Department of Psychiatry, regarding the promotion of Abilify in the geriatric population.

269. Thereafter, in January 2010, Relator was contacted by the Gary Delvecchio, Director of Compliance for U.S. Pharmaceuticals, and participated in a conference call with Mr. Delvecchio and a lawyer for the Neuroscience Division in which he discussed Dr. Richtand's concerns and his own concerns about patterns and practices of off-label promotions occurring with Abilify. In follow-up to that conference call, Relator Ibanez participated in numerous phone calls and emails with Mr. Delvecchio regarding his concerns about false and misleading advertising/data

presentations for both pediatric and geriatric use and unlawful/unsafe use of an antipsychotic such as Abilify in the geriatric patient population. In one of these emails, Relator Ibanez reported that, in a meeting discussing how to increase sales to a high quintile office where only patients 18 and under are seen, an OBS rep stated: "The Abilify message is not important…it's selling [ ] Abilify in the doctor's office not [sic] matter their specialty."

270. After raising his concerns, Mr. Ibanez began to receive negative performance reviews and experience negative attention and other retaliatory conduct in the terms and conditions of his employment.

271. By way of example, on April 12, 2010, Relator Ibanez was counseled by his superior for failing to "embrace teamwork" by objecting to inappropriate call targets. In that memorandum, Relator Ibanez's manager Keith Watters stated:

> Embraces Teamwork: (Not Meeting)
>
> Joe, since our 2009 restructuring, you have been very hesitant to embrace the new PFS targets. Since December 1, you have called me on a daily basis discussing your concern between PFS and OBS, and who should be calling on which targets. It seems as though you are very hesitant to work among your OBS colleagues with shared targets.

272. Mr. Watters also criticized that "Some of the emails you have sent to [BMS representative] Marty & [Otsuka representative] Alec are very direct and state that they should not be calling on these targets."

273. Mr. Watters' memorandum delivered other illegitimate criticisms of Relator Ibanez's performance.

274. After Relator Ibanez's concerns about illegal promotion activities went unaddressed, Relator contacted representatives of the United States to report this information.

275. The retaliatory conduct by BMS created a hostile work environment for Relator. The stress of this environment forced Relator to go on a health leave on or about May 2010.

276. While on leave, Relator continued to discuss compliance issues with the BMS Human Resources ("HR") representatives.

277. In response, HR informed him that they had begun investigating him for fraudulent sales calls.

278. The information regarding these supposed fraudulent calls were fabricated. Instead of permitting Mr. Ibanez to evaluate or rebut this information, BMS notified him that he was being terminated on or about July 16, 2010. Mr. Ibanez received his last paycheck from BMS through July 23, 2010.

279. Upon information and belief, Mr. Ibanez was terminated in retaliation for his objections to improper conduct in violation of governing laws and regulations which resulted in false claims to the United States.

2. Wrongful Termination of Relator Jennifer Derrick.

280. Relator Derrick experienced similar retaliatory conduct in Arizona. She began reporting her concerns about potential compliance issues relating to inappropriate call targets for Abilify on or about November 2, 2009.

281. In response, Ms. Derrick experienced negative attention and criticism of her performance, and her concerns were unaddressed.

282. Ms. Derrick and Mr. Ibanez had conferred over work email and work phones regarding their mutual concerns about inappropriate call targets and illegal promotion activities.

283. Mr. Ibanez also communicated to Ms. Derrick that he had reported his information to the U.S. Attorney's Office in Boston, Massachusetts.

284. Within days, on May 12, 2010, Ms. Derrick was informed she was being terminated. Like Mr. Ibanez, she was advised that they were investigating and had reached the conclusion that she had falsified sales calls.

285. These allegations are unsupported. However, Ms. Derrick was not given an opportunity to evaluate the allegations against her or rebut them. Rather, she was terminated.

286. Upon information and belief, Ms. Derrick's termination was in retaliation for her reported objections to improper conduct in violation of governing laws and regulations which resulted in false claims to the United States.

COUNT I

Violations of the False Claims Act

287. The allegations in the foregoing paragraphs are realleged as if fully set forth herein

288. The False Claims Act, 31 U.S.C. § 3729(a)(1)(A), (B), and (G) imposes liability upon, *inter alia*, those who knowingly cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim or to an obligation to pay money to the government, or those who knowingly conceal, improperly avoid or decrease an

obligation to pay money to the government. The False Claims Act, 31 U.S.C. § 3729(a)(1)(C) imposes liability on those who conspire to commit a violation of subparagraphs (A), (B), or (G).

289. From 2005 through present, Defendants knowingly caused false claims to be submitted to government healthcare programs by engaging in an off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify.

290. Defendants agreed and collaborated on illegal marketing and kickback schemes to induce increasing prescriptions of Abilify.

291. Defendants knew that these prescriptions were resulting in claims for payment to government healthcare programs.

292. Defendants' actions, if known, would have affected the United States and the States' decision to pay the resulting claims.

293. Defendants' actions violated material conditions of payment under government healthcare programs.

294. The resulting claims are noncovered and nonpayable and are false claims.

295. Defendants acted knowingly, as that term is used in the False Claims Act.

296. Defendants' knowing actions to cause the submission of false claims for payment to the United States violated 31 U.S.C. §3729(a)(1)(A).

297. Defendants have knowingly caused pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment for Abilify, knowing that such false claims would be submitted to government healthcare programs for reimbursement.

298. Defendants have also caused the states to submit false claims to the United States Government in Form CMS-64 (Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program), which falsely certified that all drugs for which federal reimbursement was sought, including Abilify, were paid for in compliance with federal law. Claims for Abilify resulting from illegal off-label marketing and illegal kickback schemes are not covered and payable by federal programs.

299. In the furtherance of this scheme, Defendants also caused to be made or used false records or statements material to a false claim in violation of 31 U.S.C. § 3729(a)(1)(B). Each illegal promotion material used to promote a drug off-label was a false record or statement material to a false claim.

300. As a result of their violations, Defendants received overpayments from government healthcare programs and failed to return the money to the Government in a timely manner. Defendants' ongoing and knowing failure to report these overpayments violates the False Claims Act, 31 U.S.C. § 3729(a)(1)(G).

301. Defendants' concerted actions to conspire to cause the submission of false claims to government healthcare programs also violates the False Claims Act, 31 U.S.C. § 3729(a)(1)(C).

302. Because the United States would not have paid for services which it knew to have been the result of illegal marketing campaigns, the United States has been harmed in an amount equal to the value paid by the United States.

303. The United States Government has been damaged as a result of Defendants' conduct in violation of the False Claims Act in an amount to be determined at trial.

COUNT II

Retaliation of Relators in Violation of the False Claims Act, 31 U.S.C. § 3730(h)

304. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

305. As alleged in above, Relators engaged in lawful acts in furtherance of efforts to stop one or more violations of 31 U.S.C. § 3729.

306. Because of Relators' lawful acts, Relators were subjected to discrimination in the terms and conditions of their employment by BMS, including but not limited to their wrongful termination.

307. The Defendant's discrimination against Relators was a violation of 31 U.S.C. § 3730(h).

308. As a consequence of Defendant's violation of 31 U.S.C. § 3730(h), Relators suffered damages.

COUNT III

Retaliation and Wrongful Discharge of Joseph Ibanez in Violation of the Ohio Whistleblower Statute, Ohio Rev. Code Ann. § 4113.52, Public Policy, and Common Law

309. The allegations in paragraphs are realleged as if fully set forth herein.

310. Relator Ibanez, during the course of his employment, became aware that the Defendant was in violation of federal laws in regard to its promotion of the drug Abilify.

311. Relator took steps to advise BMS management and other personnel of his concerns that its promotional campaigns were not compliant with federal healthcare laws.

312. Further, Relator took steps to inform the United States of his concerns that BMS practices were not compliant with federal healthcare laws.

313. As a direct and proximate consequence of his efforts, Relator Ibanez suffered retaliatory conduct by Defendant and was ultimately terminated.

314. BMS lacked an overriding legitimate business objective for terminating Relator's employment. To the contrary, Relator's termination was due to his internal reporting and objections to BMS conduct.

315. There is a clear public policy in the State of Ohio favoring the protection of whistleblowers from retaliatory acts by their employers, manifested in Ohio Rev. Code Ann. § 4113.52. There is also a clear public policy in the State of Ohio favoring adherence to federal statutes.

316. Permitting employers such as BMS to discharge employees such as Relator for internal reporting of violations of federal statutes would jeopardize these public policies.

317. Relator was retaliated against and wrongfully discharged in violation of Ohio law, as reflected by both statute and common law, including but not limited to the Ohio Whistleblower Statute, Ohio Rev. Code Ann. § 4113.52.

COUNT IV

Retaliation and Wrongful Discharge of Jennifer Derrick in Violation of the Arizona Employment Protection Act, Arizona Revised Code § 23-1501, Public Policy, and Common Law

318. The allegations in paragraphs are realleged as if fully set forth herein.

319. Relator Derrick, during the course of her employment, became aware that the Defendant was in violation of federal and comparable state laws in regard to its

illegal promotion of the drug Abilify. Such laws would include, without limitation, laws governing Medicaid coverage and Arizona statutes, A.R.S. § 36-2918 and §36-2957.

320. Relator took steps to disclose to BMS management and other personnel of her concerns that its promotional campaigns were not compliant with healthcare laws.

321. As a direct and proximate consequence of her efforts, Relator Derrick suffered retaliatory conduct by Defendant and was ultimately terminated.

322. The Arizona Employment Protection Act protects employees from the retaliatory acts of their employers for reporting violations of state laws. A.R.S. § 23-1501 (b), (c). There is a clear public policy in the State of Arizona favoring the protection of whistleblowers from retaliatory acts by their employers, and manifested by such Article.

323. Relator was retaliated against and wrongfully discharged in violation of Arizona law, as reflected by both statute and common law, including but not limited to the Arizona Employment Protection Act, A.R.S.§ 23-1501.

COUNT V

Violations of the California False Claims Act

324. The allegations in the foregoing paragraphs are realleged as if fully set forth herein.

325. The California False Claims Act, Cal. Gov. Code § 12651(a)(1)-(a)(2), imposes liability upon, *inter alia*, those who knowingly cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim.

326. Claims for payment to the California Medicaid program which resulted from illegal kickbacks and illegal promotion of drugs for noncovered and nonpayable uses are false claims.

327. From 2005 through present, Defendants knowingly caused false claims to be submitted to the California Medicaid program by engaging in an off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify. Defendants' concerted actions to cause the submission of false claims for payment to the State of California violated Cal. Gov. Code § 12651(a)(1).

328. Defendants have knowingly caused pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment for Abilify, knowing that such false claims would be submitted to the California Medicaid programs for reimbursement.

329. Thus, in the furtherance of this scheme, Defendants also caused to be made or used false records or statements material to a false claim in violation of Cal. Gov. Code § 12651(a)(2). For example, each illegal promotion material used to promote a drug off-label was a false record or statement material to a false claim.

330. Defendants acted knowingly, as that term is used in the California False Claims Act, Cal. Gov. Code § 12650(b)(3).

331. Because the State of California would not have paid for the claims resulting from Defendants' illegal schemes, the State of California has been harmed in an amount equal to the value paid by the State of California.

332. The State of California has been damaged as a result of Defendants' conduct in violation of the California False Claims Act in an amount to be determined at trial.

COUNT VI

Violations of the Colorado Medicaid False Claims Act

333. The allegations in the foregoing paragraphs are realleged as if fully set forth herein.

334. The Colorado Medicaid False Claims Act, Colo. Rev. Stat. § 25.5-4-305(1)(a)-(1)(b), imposes liability upon, *inter alia*, those who knowingly cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to false claims.

335. Claims for payment to the Colorado Medicaid program which resulted from illegal kickbacks and illegal promotion of drugs for noncovered and nonpayable uses are false claims.

336. From 2005 through present, Defendants knowingly caused false claims to be submitted to the Colorado Medicaid program by engaging in an off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify. Defendants' concerted actions to cause the submission of false claims for payment to the State of Colorado violated Colo. Rev. Stat. § 25.5-4-305(1)(a).

337. Defendants have knowingly caused pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment for Abilify, knowing that such false claims would be submitted to the Colorado Medicaid program for reimbursement.

338. Thus, in the furtherance of this scheme, Defendants also caused to be made or used false records or statements to get false claims paid or approved in violation of Colo. Rev. Stat. § 25.5-4-305(1)(b). For example, each illegal promotion material used to promote a drug off-label was a false record or statement material to a false claim.

339. Defendants acted knowingly, as that term is used in the Colorado Medicaid False Claims Act, Colo. Rev. Stat. § 25.5-4-304(3)(a).

340. Because the State of Colorado would not have paid for the claims resulting from Defendants' illegal schemes, the State of Colorado has been harmed in an amount equal to the value paid by the State of Colorado.

341. The State of Colorado has been damaged as a result of Defendants' conduct in violation of the Colorado Medicaid False Claims Act in an amount to be determined at trial.

COUNT VII

Violations of the Connecticut False Claims Act

342. The allegations in the foregoing paragraphs are realleged as if fully set forth herein.

343. The Connecticut False Claims Act, General Statute 17.319(v) § 17b-301b, imposes liability upon, *inter alia*, those who knowingly present, or cause to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval under a medical assistance program administered by the Department of Social Services, or those who knowingly make, use or cause to be made or used, a false record or statement to secure the payment or approval by the state of a false or

fraudulent claim under a medical assistance program administered by the Department of Social Services, or conspire to defraud the state by securing the allowance or payment of a false or fraudulent claim under a medical assistance program administered by the Department of Social Services.

344. Claims for payment to the Connecticut Medicaid program which resulted from illegal kickbacks and illegal promotion of drugs for noncovered and nonpayable uses are false claims.

345. From 2005 through present, Defendants knowingly caused false claims to be submitted to the Connecticut Medicaid program by engaging in an off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify. Defendants' concerted actions to cause the submission of false claims for payment to State of Connecticut violated General Statute 17.319(v) § 17b-301b.

346. Defendants have knowingly caused pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment for Abilify, knowing that such false claims would be submitted to the Connecticut Medicaid program for reimbursement.

347. Thus, in the furtherance of this scheme, Defendants also caused to be made or used false records or statements material to a false claim in violation of Connecticut False Claims Act, General Statute 17.319(v) § 17b-301b. For example, each illegal promotion material used to promote a drug off-label was a false record or statement material to a false claim.

348. Defendants acted knowingly, as that term is used in the Connecticut False Claims Act, General Statute 17.319(v) § 17b-301a.

349. Because the State of Connecticut would not have paid for the claims resulting from Defendants' illegal schemes, the State of Connecticut has been harmed in an amount equal to the value paid by the State of Connecticut.

350. The State of Connecticut has been damaged as a result of Defendants' conduct in violation of the Connecticut False Claims Act in an amount to be determined at trial.

COUNT VIII

Violations of the Delaware False Claims and Reporting Act

351. The allegations in the foregoing paragraphs are realleged as if fully set forth herein.

352. The Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1201(a)(1)-(a)(2), imposes liability upon, *inter alia*, those who knowingly cause to be presented false claims for payment or approval, and those who knowingly make or use, or cause to be made or used, false records or statements to get false claims paid or approved.

353. Claims for payment to the Delaware Medicaid program which resulted from illegal kickbacks and illegal promotion of drugs for noncovered and nonpayable uses are false claims.

354. From 2005 through present, Defendants knowingly caused false claims to be submitted to the Delaware Medicaid program by engaging in an off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify. Defendants' concerted actions to cause the submission of false claims for payment to the State of Delaware violated Del. Code Ann. tit. 6, § 1201(a)(1).

355. Defendants have knowingly caused pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment for Abilify, knowing that such false claims would be submitted to the Delaware Medicaid program for reimbursement.

356. Thus, in the furtherance of this scheme, Defendants also caused to be made or used false records or statements to get false claims paid or approved in violation of Del. Code Ann. tit. 6, § 1201(a)(2). For example, each illegal promotion material used to promote a drug off-label was a false record or statement made or used to get a false claim approved.

357. Defendants acted knowingly, as that term is used in the Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1202(3).

358. Because the State of Delaware would not have paid for the claims resulting from Defendants' illegal schemes, the State of Delaware has been harmed in an amount equal to the value paid by the State of Delaware.

359. The State of Delaware has been damaged as a result of Defendants' conduct in violation of the Delaware False Claims and Reporting Act in an amount to be determined at trial.

COUNT IX

Violations of the Florida False Claims Act

360. The allegations in the foregoing paragraphs are realleged as if fully set forth herein.

361. The Florida False Claims Act, Fla. Stat. § 68.082(2)(a)-(2)(b), imposes liability upon, *inter alia*, those who knowingly cause to be presented false claims for

payment or approval, and those who make or use, or cause to be made or used, false records or statements to get false claims paid or approved.

362. Claims for payment to the Florida Medicaid program which resulted from illegal kickbacks and illegal promotion of drugs for noncovered and nonpayable uses are false claims.

363. From 2005 through present, Defendants knowingly caused false claims to be submitted to the Florida Medicaid program by engaging in an off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify. Defendants' concerted actions to cause the submission of false claims for payment to the State of Florida violated Fla. Stat. § 68.082(2)(a).

364. Defendants have knowingly caused pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment for Abilify, knowing that such false claims would be submitted to the Florida Medicaid programs for reimbursement.

365. Thus, in the furtherance of this scheme, Defendants also caused to be made or used false records or statements to get false claims paid or approved in violation of Fla. Stat. § 68.082(2)(b). For example, each illegal promotion material used to promote a drug off-label was a false record or statement made or used to get a false claim paid or approved.

366. Defendants acted knowingly, as that term is used in the Florida False Claims Act, Fla. Stat. § 68.082(1)(c).

367. Because the State of Florida would not have paid for the claims resulting from Defendants' illegal schemes, the State of Florida has been harmed in an amount equal to the value paid by the State of Florida.

368. The State of Florida has been damaged as a result of Defendants' conduct in violation of the Florida False Claims Act in an amount to be determined at trial.

COUNT X

Violations of the Georgia False Medicaid Claims Act

369. The allegations in the foregoing paragraphs are realleged as if fully set forth herein.

370. The Georgia False Medicaid Claims Act, Ga. Code Ann. § 49-4-168.1(a)(1)-(a)(2), imposes liability upon, *inter alia*, those who knowingly cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements to get false claims paid or approved.

371. Claims for payment to the Georgia Medicaid program which resulted from illegal kickbacks and illegal promotion of drugs for noncovered and nonpayable uses are false claims.

372. From 2005 through present, Defendants knowingly caused false claims to be submitted to the Georgia Medicaid program by engaging in an off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify. Defendants' concerted actions to cause the submission of false claims for payment to the State of Georgia violated Ga. Code Ann. § 49-4-168.1(a)(1).

373. Defendants have knowingly caused pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment for Abilify, knowing that such false claims would be submitted to the Georgia Medicaid programs for reimbursement.

374. Thus, in the furtherance of this scheme, Defendants also caused to be made or used false records or statements to get false claims paid or approved violation of Ga. Code Ann. § 49-4-168.1(a)(2). For example, each illegal promotion material used to promote a drug off-label was a false record or statement made or used to get false claims paid or approved.

375. Defendants acted knowingly, as that term is used in the Georgia False Medicaid Claims Act, Ga. Code Ann. § 49-4-168(2).

376. Because the State of Georgia would not have paid for the claims resulting from Defendants' illegal schemes, the State of Georgia has been harmed in an amount equal to the value paid by the State of Georgia.

377. The State of Georgia has been damaged as a result of Defendants' conduct in violation of the Georgia False Medicaid Claims Act in an amount to be determined at trial.

COUNT XI

Violations of the Hawaii False Claims Act

378. The allegations in the foregoing paragraphs are realleged as if fully set forth herein.

379. The Hawaii False Claims Act, Haw. Rev. Stat. § 661-21(a)(1)-(a)(2), imposes liability upon, *inter alia*, those who knowingly cause to be presented false

claims for payment or approval, and those who knowingly make or use, or cause to be made or used, false records or statements to get false claims paid or approved.

380. Claims for payment to the Hawaii Medicaid program which resulted from illegal kickbacks and illegal promotion of drugs for noncovered and nonpayable uses are false claims.

381. From 2005 through present, Defendants knowingly caused false claims to be submitted to the Hawaii Medicaid program by engaging in an off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify. Defendants' concerted actions to cause the submission of false claims for payment to the State of Hawaii violated Haw. Rev. Stat. § 661-21(a)(1).

382. Defendants have knowingly caused pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment for Abilify, knowing that such false claims would be submitted to the Hawaii Medicaid program for reimbursement.

383. Thus, in the furtherance of this scheme, Defendants also caused to be made or used false records or statements to get false claims paid or approved in violation of Haw. Rev. Stat. § 661-21(a)(2). For example, each illegal promotion material used to promote a drug off-label was a false record or statement made or used to get a false claim paid or approved.

384. Defendants acted knowingly, as that term is used in the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21(e).

385. Because the State of Hawaii would not have paid for the claims resulting from Defendants' illegal schemes, the State of Hawaii has been harmed in an amount equal to the value paid by the State of Hawaii.

386. The State of Hawaii has been damaged as a result of Defendants' conduct in violation of the Hawaii False Claims Act in an amount to be determined at trial.

COUNT XII

Violations of Illinois False Claims Act

387. The allegations in the foregoing paragraphs are realleged as if fully set forth herein.

388. The Illinois False Claims Act, 740 Ill. Comp. Stat. 175/3(a)(1)(A)-(a)(1)(B), imposes liability upon, *inter alia*, those who knowingly cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim.

389. Claims for payment to the Illinois Medicaid program which resulted from illegal kickbacks and illegal promotion of drugs for noncovered and nonpayable uses are false claims.

390. From 2005 through present, Defendants knowingly caused false claims to be submitted to the Illinois Medicaid program by engaging in an off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify. Defendants' concerted actions to cause the submission of false claims for payment to the State of Illinois violated 740 Ill. Comp. Stat. 175/3(a)(1)(A).

391. Defendants have knowingly caused pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment for Abilify,

knowing that such false claims would be submitted to the Illinois Medicaid programs for reimbursement.

392. Thus, in the furtherance of this scheme, Defendants also caused to be made or used false records or statements material to a false claim in violation of 740 Ill. Comp. Stat. 175/3(a)(1)(B). For example, each illegal promotion material used to promote a drug off-label was a false record or statement material to a false claim.

393. Defendants acted knowingly, as that term is used in the Illinois False Claims Act, 740 Ill. Comp. Stat. 175/3(b)(1).

394. Because the State of Illinois would not have paid for the claims resulting from Defendants' illegal schemes, the State of Illinois has been harmed in an amount equal to the value paid by the State of Illinois.

395. The State of Illinois has been damaged as a result of Defendants' conduct in violation of the Illinois False Claims Act in an amount to be determined at trial.

COUNT XIII

Violations of the Ind. Code § 5-11-5.5-2(b)(1)-(b)(2)

396. The allegations in the foregoing paragraphs are realleged as if fully set forth herein.

397. Indiana law, Ind. Code § 5-11-5.5-2(b)(1)-(b)(2), imposes liability upon, *inter alia*, those who knowingly cause to be presented false claims for payment or approval, and those who knowingly make or use, or cause to be made or used, false records or statements to obtain payment or approval of false claims.

398. Claims for payment to the Indiana Medicaid program which resulted from illegal kickbacks and illegal promotion of drugs for noncovered and nonpayable uses are false claims.

399. From 2005 through present, Defendants knowingly caused false claims to be submitted to the Indiana Medicaid program by engaging in an off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify. Defendants' concerted actions to cause the submission of false claims for payment to the State of Indiana violated Ind. Code § 5-11-5.5-2(b)(1).

400. Defendants have knowingly caused pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment for Abilify, knowing that such false claims would be submitted to the Indiana Medicaid program for reimbursement.

401. Thus, in the furtherance of this scheme, Defendants also caused to be made or used false records or statements to obtain payment or approval of false claims in violation of Ind. Code § 5-11-5.5-2(b)(2). For example, each illegal promotion material used to promote a drug off-label was a false record or statement made or used to obtain payment or approval of a false claim.

402. Defendants acted knowingly, as that term is defined in Ind. Code § 5-11-5.5-1(4).

403. Because the State of Indiana would not have paid for the claims resulting from Defendants' illegal schemes, the State of Indiana has been harmed in an amount equal to the value paid by the State of Indiana.

404. The State of Indiana has been damaged as a result of Defendants' conduct in violation of Indiana law in an amount to be determined at trial.

COUNT XIV

Violations of the Iowa False Claims Law

405. The allegations in the foregoing paragraphs are realleged as if fully set forth herein.

406. The Iowa False Claims Law, Iowa Law 15.5, § 685.2 imposes liability upon, *inter alia*, any person who knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; or conspires to commit a violation of paragraph "a", or "b".

407. Claims for payment to the Iowa Medicaid program which resulted from illegal kickbacks and illegal promotion of drugs for noncovered and nonpayable uses are false claims.

408. From 2005 through present, Defendants knowingly caused false claims to be submitted to the Iowa Medicaid program by engaging in an off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify. Defendants' concerted actions to cause the submission of false claims for payment to the State of Iowa violated Iowa Law 15.5, § 685.2.

409. Defendants have knowingly caused pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment for Abilify, knowing that such false claims would be submitted to the Iowa Medicaid programs for reimbursement.

410. Thus, in the furtherance of this scheme, Defendants also caused to be made or used false records or statements material to a false claim in violation of Iowa Law 15.5, § 685.2. For example, each illegal promotion material used to promote a drug off-label was a false record or statement material to a false claim.

411. Defendants acted knowingly, as that term is used in the Iowa False Claims Law, Iowa Law 15.5 § 685.1.

412. Because the State of Iowa would not have paid for the claims resulting from Defendants' illegal schemes, the State of Iowa has been harmed in an amount equal to the value paid by the State of Iowa.

413. The State of Iowa has been damaged as a result of Defendants' conduct in violation of the Iowa False Claims Law in an amount to be determined at trial.

COUNT XV

Violations of the Louisiana Medical Assistance Programs Integrity Law

414. The allegations in the foregoing paragraphs are realleged as if fully set forth herein.

415. The Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. § 46:438.3(A)-(B), imposes liability upon, *inter alia*, those who knowingly cause to be presented false claims for payment or approval, and those who knowingly make or use, or cause to be made or used, false records or statements material false claims.

416. Claims for payment to the Louisiana Medicaid program which resulted from illegal kickbacks and illegal promotion of drugs for noncovered and nonpayable uses are false claims.

417. From 2005 through present, Defendants knowingly caused false claims to be submitted to the Louisiana Medicaid program by engaging in an off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify. Defendants' concerted actions to cause the submission of false claims for payment to the State of Louisiana violated La. Rev. Stat. § 46:438.3(A).

418. Defendants have knowingly caused pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment for Abilify, knowing that such false claims would be submitted to the Louisiana Medicaid program for reimbursement.

419. Thus, in the furtherance of this scheme, Defendants also caused to be made or used false records or statements material false claims in violation of La. Rev. Stat. § 46:438.3(B). For example, each illegal promotion material used to promote a drug off-label was a false record or statement material to a false claim.

420. Defendants acted knowingly, as that term is used in the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. § 46:437.3(11).

421. Because the State of Louisiana would not have paid for the claims resulting from Defendants' illegal schemes, the State of Louisiana has been harmed in an amount equal to the value paid by the State of Louisiana.

422. The State of Louisiana has been damaged as a result of Defendants' conduct in violation of the Louisiana Medical Assistance Programs Integrity Law in an amount to be determined at trial.

COUNT XVI

Violations of the Maryland False Health Claims Act

423. The allegations in the foregoing paragraphs are realleged as if fully set forth herein.

424. The Maryland False Health Claims Act, Md. Code. Ann., Health-Gen. § 2-602(a)(1)-(a)(2), imposes liability upon, *inter alia*, those who knowingly cause to be presented false claims for payment or approval, and those who knowingly make or use, or cause to be made or used, false records or statements material to false claims.

425. Claims for payment to the Maryland Medicaid program which resulted from illegal kickbacks and illegal promotion of drugs for noncovered and nonpayable uses are false claims.

426. From 2005 through present, Defendants knowingly caused false claims to be submitted to the Maryland Medicaid program by engaging in an off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify. Defendants' concerted actions to cause the submission of false claims for payment to the State of Maryland violated Md. Code. Ann., Health-Gen. § 2-602(a)(1).

427. Defendants have knowingly caused pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment for Abilify, knowing that such false claims would be submitted to the Maryland Medicaid program for reimbursement.

428. Thus, in the furtherance of this scheme, Defendants also caused to be made or used false records or statements material to false claims in violation of Md. Code. Ann., Health-Gen. § 2-602(a)(2). For example, each illegal promotion material

used to promote a drug off-label was a false record or statement material to a false claim.

429. Defendants acted knowingly, as that term is used in the Maryland False Health Claims Act, Md. Code. Ann., Health-Gen. § 2-601(f).

430. Because the State of Maryland would not have paid for the claims resulting from the Defendants' illegal schemes, the State of Maryland has been harmed in an amount equal to the value paid by the State of Maryland.

431. The State of Maryland has been damaged as a result of Defendants' conduct in violation of the Maryland False Health Claims Act in an amount to be determined at trial.

COUNT XVII

Violations of the Massachusetts False Claims Act

432. The allegations in the foregoing paragraphs are realleged as if fully set forth herein.

433. The Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, § 5B(1)-(2), imposes liability upon, *inter alia*, those who knowingly cause to be presented false claims for payment or approval, and those who knowingly make or use, or cause to be made or used, false records or statements to obtain payment or approval of a claim.

434. Claims for payment to the Massachusetts Medicaid program which resulted from illegal kickbacks and illegal promotion of drugs for noncovered and nonpayable uses are false claims.

435. From 2005 through present, Defendants knowingly caused false claims to be submitted to the Massachusetts Medicaid program by engaging in an off-label

marketing campaign and illegal kickback schemes to induce the prescribing of Abilify. Defendants' concerted actions to cause the submission of false claims for payment to the Commonwealth of Massachusetts violated Mass. Gen. Laws ch. 12, § 5B(1).

436. Defendants have knowingly caused pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment for Abilify, knowing that such false claims would be submitted to the Massachusetts Medicaid program for reimbursement.

437. Thus, in the furtherance of this scheme, Defendants also caused to be made or used false records or statements to obtain payment or approval of claims in violation of Mass. Gen. Laws ch. 12, § 5B(2). For example, each illegal promotion material used to promote a drug off-label was a false record or statement made or used to obtain payment or approval of a claim.

438. Defendants acted knowingly, as that term is used in the Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, § 5A(a).

439. Because the Commonwealth of Massachusetts would not have paid for the claims resulting from Defendants' illegal schemes, the Commonwealth of Massachusetts has been harmed in an amount equal to the value paid by the Commonwealth of Massachusetts.

440. The Commonwealth of Massachusetts has been damaged as a result of Defendants' conduct in violation of the Massachusetts False Claims Act in an amount to be determined at trial.

COUNT XVIII

Violations of the Michigan Medicaid False Claims Act

441. The allegations in the foregoing paragraphs are realleged as if fully set forth herein.

442. The Michigan Medicaid False Claims Act, Mich. Comp. Laws § 400.607(1), imposes liability upon, *inter alia*, those who knowingly cause to be presented false claims for payment or approval.

443. Claims for payment to the Michigan Medicaid program which resulted from illegal kickbacks and illegal promotion of drugs for noncovered and nonpayable uses are false claims.

444. From 2005 through present, Defendants knowingly caused false claims to be submitted to the Michigan Medicaid program by engaging in an off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify. Defendants' concerted actions to cause the submission of false claims for payment to the State of Michigan violated Mich. Comp. Laws § 400.607(1).

445. Defendants have knowingly caused pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment for Abilify, knowing that such false claims would be submitted to the Michigan Medicaid program for reimbursement.

446. Defendants acted knowingly, as that term is used in the Michigan Medicaid False Claims Act, Mich. Comp. Laws § 400.602(f).

447. Because the State of Michigan would not have paid for the claims resulting from Defendants' illegal schemes, the State of Michigan has been harmed in an amount equal to the value paid by the State of Michigan.

448. The State of Michigan has been damaged as a result of Defendants' conduct in violation of the Michigan Medicaid False Claims Act in an amount to be determined at trial.

COUNT XIX

Violations of the Minn. Stat. § 15C.02(a)(1)-(a)(2)

449. The allegations in the foregoing paragraphs are realleged as if fully set forth herein.

450. Minnesota Law, Minn. Stat. § 15C.02(a)(1)-(a)(2), imposes liability upon, *inter alia*, those who knowingly cause to be presented false claims for payment or approval, and those who knowingly make or use, or cause to be made or used, false records or statements to get false claims paid or approved.

451. Claims for payment to the Minnesota Medicaid program which resulted from illegal kickbacks and illegal promotion of drugs for noncovered and nonpayable uses are false claims.

452. From 2005 through present, Defendants knowingly caused false claims to be submitted to the Minnesota Medicaid program by engaging in an off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify. Defendants' concerted actions to cause the submission of false claims for payment to the State of Minnesota violated Minn. Stat. § 15C.02(a)(1).

453. Defendants have knowingly caused pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment for Abilify, knowing that such false claims would be submitted to the Minnesota Medicaid program for reimbursement.

454. Thus, in the furtherance of this scheme, Defendants also caused to be made or used false records or statements to get false claims paid or approved in violation of Minn. Stat. § 15C.02(a)(2). For example, each illegal promotion material used to promote a drug off-label was a false record or statement made or used to get a false claim paid or approved.

455. Defendants acted knowingly, as that term is defined in Minn. Stat. § 15C.01(3).

456. Because the State of Minnesota would not have paid for the claims resulting from Defendants' illegal schemes, the State of Minnesota has been harmed in an amount equal to the value paid by the State of Minnesota.

457. The State of Minnesota has been damaged as a result of Defendants' conduct in violation of Minnesota law in an amount to be determined at trial.

COUNT XX

Violations of the Montana False Claims Act

458. The allegations in the foregoing paragraphs are realleged as if fully set forth herein.

459. The Montana False Claims Act, Mont. Code Ann. § 17-8-403(1)(a)-(1)(b), imposes liability upon, *inter alia*, those who knowingly cause to be presented false

claims for payment or approval, and those who knowingly make or use, or cause to be made or used, false records or statements to get false claims paid or approved.

460. Claims for payment to the Montana Medicaid program which resulted from illegal kickbacks and illegal promotion of drugs for noncovered and nonpayable uses are false claims.

461. From 2005 through present, Defendants knowingly caused false claims to be submitted to the Montana Medicaid program by engaging in an off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify. Defendants' concerted actions to cause the submission of false claims for payment to the State of Montana violated Mont. Code Ann. § 17-8-403(1)(a).

462. Defendants have knowingly caused pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment for Abilify, knowing that such false claims would be submitted to the Montana Medicaid program for reimbursement.

463. Thus, in the furtherance of this scheme, Defendants also caused to be made or used false records or statements to get false claims paid or approved in violation of Mont. Code Ann. § 17-8-403(1)(b). For example, each illegal promotion material used to promote a drug off-label was a false record or statement made or used to get a false claim paid or approved.

464. Defendants acted knowingly, as that term is used in the Montana False Claims Act, Mont. Code Ann. § 17-8-402(4)(a).

465. Because the State of Montana would not have paid for the claims resulting from Defendants' illegal schemes, the State of Montana has been harmed in an amount equal to the value paid by the State of Montana.

466. The State of Montana has been damaged as a result of Defendants' conduct in violation of the Montana False Claims Act in an amount to be determined at trial.

COUNT XXI

Violations of the Nev. Rev. Stat. § 357.040(1)(a)-(1)(b)

467. The allegations in the foregoing paragraphs are realleged as if fully set forth herein.

468. Nevada Law, Nev. Rev. Stat. § 357.040(1)(a)-(1)(b), imposes liability upon, *inter alia*, those who knowingly cause to be presented false claims for payment or approval, and those who knowingly make or use, or cause to be made or used, false records or statements to obtain payment or approval of false claims.

469. Claims for payment to the Nevada Medicaid program which resulted from illegal kickbacks and illegal promotion of drugs for noncovered and nonpayable uses are false claims.

470. From 2005 through present, Defendants knowingly caused false claims to be submitted to the Nevada Medicaid program by engaging in an off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify. Defendants' concerted actions to cause the submission of false claims for payment to the State of Nevada violated Nev. Rev. Stat. § 357.040(2).

471. Defendants have knowingly caused pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment for Abilify, knowing that such false claims would be submitted to the Nevada Medicaid program for reimbursement.

472. Thus, in the furtherance of this scheme, Defendants also caused to be made or used false records or statements to obtain payment or approval of false claims in violation of Nev. Rev. Stat. § 357.040(1)(b). For example, each illegal promotion material used to promote a drug off-label was a false record or statement made or used to obtain payment or approval of a false claim.

473. Defendants acted knowingly, as that term is defined in Nev. Rev. Stat. § 357.040(1)(a)-(1)(b)

474. Because the State of Nevada would not have paid for the claims resulting from Defendants' illegal schemes, the State of Nevada has been harmed in an amount equal to the value paid by the State of Nevada.

475. The State of Nevada has been damaged as a result of Defendants' conduct in violation of Nevada law in an amount to be determined at trial.

COUNT XXIII

Violations of the New Jersey False Claims Act

476. The allegations in the foregoing paragraphs are realleged as if fully set forth herein.

477. The New Jersey False Claims Act, N.J. Stat. Ann. § 2A:32C-3(a)-(b), imposes liability upon, *inter alia*, those who knowingly cause to be presented false

claims for payment or approval, and those who knowingly make or use, or cause to be made or used, false records or statements to get false claims paid or approved.

478. Claims for payment to the New Jersey Medicaid program which resulted from illegal kickbacks and illegal promotion of drugs for noncovered and nonpayable uses are false claims.

479. From 2005 through present, Defendants knowingly caused false claims to be submitted to the New Jersey Medicaid program by engaging in an off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify. Defendants' concerted actions to cause the submission of false claims for payment to the State of New Jersey violated N.J. Stat. Ann. § 2A:32C-3(a).

480. Defendants have knowingly caused pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment for Abilify, knowing that such false claims would be submitted to the New Jersey Medicaid program for reimbursement.

481. Thus, in the furtherance of this scheme, Defendants also caused to be made or used false records or statements to get false claims paid or approved in violation of N.J. Stat. Ann. § 2A:32C-3(b). For example, each illegal promotion material used to promote a drug off-label was a false record or statement made or used to get a false claim paid or approved.

482. Defendants acted knowingly, as that term is used in the New Jersey False Claims Act, N.J. Stat. Ann. § 2A:32C-2.

483. Because the State of New Jersey would not have paid for the claims resulting from Defendants' illegal schemes, the State of New Jersey has been harmed in an amount equal to the value paid by the State of New Jersey.

484. The State of New Jersey has been damaged as a result of Defendants' conduct in violation of the New Jersey False Claims Act in an amount to be determined at trial.

COUNT XXIV

Violations of the New Mexico Medicaid False Claims Act and the New Mexico Fraud Against Taxpayers Act

485. The allegations in the foregoing paragraphs are realleged as if fully set forth herein.

486. The New Mexico Medicaid, N.M. Stat. Ann. § 27-14-4(A) and (C), imposes liability upon, *inter alia*, those who knowingly present or cause to be presented false claims to the New Mexico Medicaid program, and those who make or use, or cause to be made or used, false records or statements to get false claims paid or approved.

487. The New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. § 44-9-3(A)(1) and (2) imposes liability upon, inter alia, those who knowingly present or cause to be presented false claims, and those who make or use, or cause to be made or used, false records or statements to get false claims paid or approved.

488. Claims for payment to the New Mexico Medicaid program which resulted from illegal kickbacks and illegal promotion of drugs for noncovered and nonpayable uses are false claims.

489. From 2005 through present, Defendants knowingly caused false claims to be submitted to the New Mexico Medicaid program by engaging in an off-label

marketing campaign and illegal kickback schemes to induce the prescribing of Abilify. Defendants' concerted actions to cause the submission of false claims for payment to the State of Mexico violated N.M. Stat. Ann. § 27-14-4(A) and 44-9-3(A)(1).

490. Defendants have knowingly caused pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment for Abilify, knowing that such false claims would be submitted to the New Mexico Medicaid program for reimbursement.

491. Thus, in the furtherance of this scheme, Defendants also knowingly caused to be made or used false records or statements to get false claims paid or approved in violation of N.M. Stat. Ann. § 27-14-4(C) and 44-9-3(A)(2). For example, each illegal promotion material used to promote a drug off-label was a false record or statement made or used to get a false claim paid or approved.

492. Because the State of New Mexico would not have paid for the claims resulting from Defendants' illegal schemes, the State of New Mexico has been harmed in an amount equal to the value paid by the State of New Mexico.

493. The State of New Mexico has been damaged as a result of Defendants' conduct in violation of the New Mexico Medicaid False Claims Act and the New Mexico Fraud Against Taxpayers Act in an amount to be determined at trial.

COUNT XXV

Violations of the New York False Claims Act

494. The allegations in the foregoing paragraphs are realleged as if fully set forth herein.

495. The New York False Claims Act, N.Y. State Fin. Law § 189(1)(a)-(1)(b), imposes liability upon, *inter alia*, those who knowingly cause to be presented false claims for payment or approval, and those who knowingly make or use, or cause to be made or used, false records or statements material to false claims.

496. Claims for payment to the New York Medicaid program which resulted from illegal kickbacks and illegal promotion of drugs for noncovered and nonpayable uses are false claims.

497. From 2005 through present, Defendants knowingly caused false claims to be submitted to the New York Medicaid program by engaging in an off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify. Defendants' concerted actions to cause the submission of false claims for payment to the State of New York violated N.Y. State Fin. Law § 189(1)(a).

498. Defendants have knowingly caused pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment for Abilify, knowing that such false claims would be submitted to the New York Medicaid program for reimbursement.

499. Thus, in the furtherance of this scheme, Defendants also caused to be made or used false records or statements material to false claims in violation of N.Y. State Fin. Law § 189(1)(b). For example, each illegal promotion material used to promote a drug off-label was a false record or statement material to a false claim.

500. Defendants acted knowingly, as that term is used in the New York False Claims Act, N.Y. State Fin. Law § 188(3).

501. Because the State of New York would not have paid for the claims resulting from Defendants' illegal schemes, the State of New York has been harmed in an amount equal to the value paid by the State of New York.

502. The State of New York has been damaged as a result of Defendants' conduct in violation of the New York False Claims Act in an amount to be determined at trial.

COUNT XXVI

Violations of the North Carolina False Claims Act

503. The allegations in the foregoing paragraphs are realleged as if fully set forth herein.

504. The North Carolina False Claims Act, N.C. Gen. Stat. § 1-607(a)(1)-(a)(2), imposes liability upon, *inter alia*, those who knowingly cause to be presented false claims for payment or approval, and those who knowingly make or use, or cause to be made or used, false records or statements material to false claims.

505. Claims for payment to the North Carolina Medicaid program which resulted from illegal kickbacks and illegal promotion of drugs for noncovered and nonpayable uses are false claims.

506. From 2005 through present, Defendants knowingly caused false claims to be submitted to the North Carolina Medicaid program by engaging in an off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify. Defendants' concerted actions to cause the submission of false claims for payment to the State of North Carolina violated N.C. Gen. Stat. § 1-607(a)(1).

507. Defendants have knowingly caused pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment for Abilify, knowing that such false claims would be submitted to the North Carolina Medicaid program for reimbursement.

508. Thus, in the furtherance of this scheme, Defendants also caused to be made or used false records or statements material to false claims in violation of N.C. Gen. Stat. § 1-607(a)(2). For example, each illegal promotion material used to promote a drug off-label was a false record or statement material to a false claim.

509. Defendants acted knowingly, as that term is used in the North Carolina False Claims Act, N.C. Gen. Stat. § 1-606(4).

510. Because the State of North Carolina would not have paid for the claims resulting from Defendants' illegal schemes, the State of North Carolina has been harmed in an amount equal to the value paid by the State of North Carolina.

511. Because The State of North Carolina has been damaged as a result of Defendants' conduct in violation of the North Carolina False Claims Act in an amount to be determined at trial.

COUNT XXVII

Violations of the Oklahoma Medicaid False Claims Act

512. The allegations in the foregoing paragraphs are realleged as if fully set forth herein.

513. The Oklahoma Medicaid False Claims Act**,** Okla. Stat. tit. 63, § 5053.1(B)(1)-(B)(2), imposes liability upon, *inter alia*, those who knowingly cause to be presented false claims for payment or approval, and those who knowingly make or use,

or cause to be made or used, false records or statements to get false claims paid or approved.

514. Claims for payment to the Oklahoma Medicaid program which resulted from illegal kickbacks and illegal promotion of drugs for noncovered and nonpayable uses are false claims.

515. From 2005 through present, Defendants knowingly caused false claims to be submitted to the Oklahoma Medicaid program by engaging in an off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify. Defendants' concerted actions to cause the submission of false claims for payment to the State of Oklahoma violated Okla. Stat. tit. 63, § 5053.1(B)(1).

516. Defendants have knowingly caused pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment for Abilify, knowing that such false claims would be submitted to the Oklahoma Medicaid program for reimbursement.

517. Thus, in the furtherance of this scheme, Defendants also caused to be made or used false records or statements to get false claims paid or approved in violation of Okla. Stat. tit. 63, § 5053.1(B)(2). For example, each illegal promotion material used to promote a drug off-label was a false record or statement made or used to get a false claim paid or approved.

518. Defendants acted knowingly, as that term is used in the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, § 5053.1(A)(1).

519. Because the State of Oklahoma would not have paid for the claims resulting from Defendants' illegal schemes, the State of Oklahoma has been harmed in an amount equal to the value paid by the State of Oklahoma.

520. The State of Oklahoma has been damaged as a result of Defendants' conduct in violation of the Oklahoma Medicaid False Claims Act in an amount to be determined at trial.

COUNT XXVIII

Violations of the Rhode Island False Claims Act

521. The allegations in the foregoing paragraphs are realleged as if fully set forth herein.

522. The Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-3(a)(1)-(a)(2), imposes liability upon, *inter alia*, those who knowingly cause to be presented false claims for payment or approval, and those who knowingly make or use, or cause to be made or used, false records or statements to get false claims paid or approved.

523. Claims for payment to the Rhode Island Medicaid program which resulted from illegal kickbacks and illegal promotion of drugs for noncovered and nonpayable uses are false claims.

524. From 2005 through present, Defendants knowingly caused false claims to be submitted to the Rhode Island Medicaid program by engaging in an off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify. Defendants' concerted actions to cause the submission of false claims for payment to the State of Rhode Island violated R.I. Gen. Laws § 9-1.1-3(a)(1).

525. Defendants have knowingly caused pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment for Abilify, knowing that such false claims would be submitted to the Rhode Island Medicaid program for reimbursement.

526. Thus, in the furtherance of this scheme, Defendants also caused to be made or used false records or statements to get false claims paid or approved in violation of R.I. Gen. Laws § 9-1.1-3(a)(2). For example, each illegal promotion material used to promote a drug off-label was a false record or statement made or used to get a false claim paid or approved.

527. Defendants acted knowingly, as that term is used in the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-3(b).

528. Because the State of Rhode Island would not have paid for the claims resulting from Defendants' illegal schemes, the State of Rhode Island has been harmed in an amount equal to the value paid by the State of Rhode Island.

529. The State of Rhode Island has been damaged as a result of Defendants' conduct in violation of the Rhode Island False Claims Act in an amount to be determined at trial.

COUNT XXIX

Violations of the Tennessee Medicaid False Claims Act

530. The allegations in the foregoing paragraphs are realleged as if fully set forth herein.

531. The Tennessee Medicaid False Claims Act**,** Tenn. Code Ann. § 4-18-103(a)(1)-(a)(2), imposes liability upon, *inter alia*, those who knowingly cause to be

presented false claims for payment or approval, and those who knowingly make or use, or cause to be made or used, false records or statements to get false claims paid or approved.

532. Claims for payment to the Tennessee Medicaid program which resulted from illegal kickbacks and illegal promotion of drugs for noncovered and nonpayable uses are false claims.

533. From 2005 through present, Defendants knowingly caused false claims to be submitted to the Tennessee Medicaid program by engaging in an off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify. Defendants' concerted actions to cause the submission of false claims for payment to the State of Tennessee violated Tenn. Code Ann. § 4-18-103(a)(1).

534. Defendants have knowingly caused pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment for Abilify, knowing that such false claims would be submitted to the Tennessee Medicaid program for reimbursement.

535. Thus, in the furtherance of this scheme, Defendants also caused to be made or used false records or statements to get false claims paid or approved in violation of Tenn. Code Ann. § 4-18-103(a)(2). For example, each illegal promotion material used to promote a drug off-label was a false record or statement made or used to get a false claim paid or approved.

536. Defendants acted knowingly, as that term is used in the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 4-18-102(2).

537. Because the State of Tennessee would not have paid for the claims resulting from Defendants' illegal schemes, the State of Tennessee has been harmed in an amount equal to the value paid by the State of Tennessee.

538. The State of Tennessee has been damaged as a result of Defendants' conduct in violation of the Tennessee Medicaid False Claims Act in an amount to be determined at trial.

COUNT XXX

Violations of Tex. Hum. Res. Code Ann. § 36.002(1)

539. The allegations in the foregoing paragraphs are realleged as if fully set forth herein.

540. Texas law, Tex. Hum. Res. Code Ann. § 36.002(1)-(13) imposes liability upon, *inter alia*, those who knowingly cause to be made false statements or misrepresentations of a material fact to permit a person to receive a benefit or payment under the Medicaid program that is not authorized.

541. Claims for payment to the Texas Medicaid program which resulted from illegal kickbacks and illegal promotion of drugs for noncovered and nonpayable uses are false claims.

542. From 2005 through present, Defendants knowingly caused false claims to be submitted to the Texas Medicaid program by engaging in an off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify. Defendants' concerted actions to cause the submission of false claims for payment to the State of Texas violated Tex. Hum. Res. Code Ann. 36.002(13).

543. Defendants have knowingly caused pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other documents to the Texas Medicaid programs to for payment. These documents falsely misrepresented that the amounts to be paid were reimburseable by the Texas Medicaid program, when in fact they were not. By causing pharmacies and other healthcare providers to submit misrepresentations of material fact to the Texas Medicaid program, Defendants violated Tex. Hum. Res. Code Ann. § 36.002(1).

544. Claims for payment to the Texas Medicaid program which resulted from illegal kickbacks and illegal promotion of drugs for noncovered and nonpayable uses contain misrepresentations that such claims are reimburseable. The misrepresentations Defendants caused to be submitted were material because they had a natural tendency to effect the decision of the Texas Medicaid program to pay claims supported by the misrepresentations

545. Defendants acted knowingly, as that term is used in Tex. Hum. Res. Code Ann. § 36.0011(a).

546. Because the State of Texas would not have paid for the claims resulting from Defendants' illegal schemes, the State of Texas has been harmed in an amount equal to the value paid by the State of Texas.

547. The State of Texas has been damaged as a result of Defendants' conduct in violation of Texas law in an amount to be determined at trial.

COUNT XXXI

Violations of the Virginia Fraud Against Taxpayers Act

548. The allegations in the foregoing paragraphs are realleged as if fully set forth herein.

549. The Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(A)(1)-(A)(2), imposes liability upon, *inter alia*, those who knowingly cause to be presented false claims for payment or approval, and those who knowingly make or use, or cause to be made or used, false records or statements to get false claims paid or approved.

550. Claims for payment to the Virginia Medicaid program which resulted from illegal kickbacks and illegal promotion of drugs for noncovered and nonpayable uses are false claims.

551. From 2005 through present, Defendants knowingly caused false claims to be submitted to the Virginia Medicaid program by engaging in an off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify. Defendants' concerted actions to cause the submission of false claims for payment to the Commonwealth of Virginia violated Va. Code Ann. § 8.01-216.3(A)(1).

552. Defendants have knowingly caused pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment for Abilify, knowing that such false claims would be submitted to the Virginia Medicaid program for reimbursement.

553. Thus, in the furtherance of this scheme, Defendants also caused to be made or used false records or statements to get false claims paid or approved in

violation of Va. Code Ann. § 8.01-216.3(A)(2). For example, each illegal promotion material used to promote a drug off-label was a false record or statement made or used to get a false claim paid or approved.

554. Defendants acted knowingly, as that term is used in the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(C).

555. Because the Commonwealth of Virginia would not have paid for the claims resulting from Defendants' illegal schemes, the Commonwealth of Virginia has been harmed in an amount equal to the value paid by the Commonwealth of Virginia.

556. The Commonwealth of Virginia has been damaged as a result of Defendants' conduct in violation of the Virginia Fraud Against Taxpayers Act in an amount to be determined at trial.

COUNT XXXII

Violations of the Washington Health Care False Claim Act.

557. The allegations in the foregoing paragraphs are realleged as if fully set forth herein.

558. The Washington Health Care False Claim Act, RCW 48.80 § 030 imposes liability upon, *inter alia*, any person who makes or presents or causes to be presented to a health care payer, a claim for health care payment knowing the claim to be false; or knowingly presents to a health care payer a claim for a health care payment that falsely represents that the goods or services were medically necessary in accordance with professionally accepted standards.

559. Claims for payment to the Washington Medicaid program which resulted from illegal kickbacks and illegal promotion of drugs for noncovered and nonpayable uses are false claims.

560. From 2005 through present, Defendants knowingly caused false claims to be submitted to the Washington Medicaid program by engaging in an off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify. Defendants' concerted actions to cause the submission of false claims for payment to the State of Washington violated Washington Law, RCW 48.80 § 030.

561. Defendants have knowingly caused pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment for Abilify, knowing that such false claims would be submitted to the Washington Medicaid programs for reimbursement.

562. Thus, in the furtherance of this scheme, Defendants also caused to be made or used false records or statements material to a false claim in violation of Washington Health Care False Claim Act, RCW 48.80 § 030. For example, each illegal promotion material used to promote a drug off-label was a false record or statement material to a false claim.

563. Defendants acted knowingly, as that term is used in the Washington Health Care False Claim Act, RCW 48.80 § 020.

564. Because the State of Washington would not have paid for the claims resulting from Defendants' illegal schemes, the State of Washington has been harmed in an amount equal to the value paid by the State of Washington.

565. The State of Washington has been damaged as a result of Defendants' conduct in violation of the Washington False Claim Act in an amount to be determined at trial.

COUNT XXXIII

Violations of the Wisconsin False Claims for Medical Assistance Law

566. The allegations in the foregoing paragraphs are realleged as if fully set forth herein.

567. The Wisconsin False Claims for Medical Assistance Law, Wis. Stat. § 20.931(2)(a)-(2)(b), imposes liability upon, *inter alia*, those who knowingly cause to be presented false claims for payment or approval, and those who knowingly make or use, or cause to be made or used, false records or statements to obtain approval or payment of false claims.

568. Claims for payment to the Wisconsin Medicaid program which resulted from illegal kickbacks and illegal promotion of drugs for noncovered and nonpayable uses are false claims.

569. From 2005 through present, Defendants knowingly caused false claims to be submitted to the Wisconsin Medicaid program by engaging in an off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify. Defendants' concerted actions to cause the submission of false claims for payment to the State of Wisconsin violated Wis. Stat. § 20.931(2)(a).

570. Defendants have knowingly caused pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment for Abilify,

knowing that such false claims would be submitted to the Wisconsin Medicaid program for reimbursement.

571. Thus, in the furtherance of this scheme, Defendants also caused to be made or used false records or statements to obtain approval or payment of false claims in violation of Wis. Stat. § 20.931(2)(b). For example, each illegal promotion material used to promote a drug off-label was a false record or statement made or used to obtain approval or payment of a false claim.

572. Defendants acted knowingly, as that term is defined in Wis. Stat. § 20.931(1)(d).

573. Because the State of Wisconsin would not have paid for the claims resulting from Defendants' illegal schemes, the State of Wisconsin has been harmed in an amount equal to the value paid by the State of Wisconsin.

574. The State of Wisconsin has been damaged as a result of Defendants' conduct in violation of the Wisconsin False Claims for Medical Assistance Law in an amount to be determined at trial.

COUNT XXXIV

Violations of the District of Columbia False Claims Act

575. The allegations in the foregoing paragraphs are realleged as if fully set forth herein.

576. The District of Columbia False Claims Act, D.C. Code § 2-308.14(a)(1)-(a)(2), imposes liability upon, *inter alia*, those who knowingly cause to be presented false claims for payment or approval, and those who knowingly make or use, or cause to be made or used, false records or statements to get false claims paid or approved.

577. Claims for payment to the District of Columbia Medicaid program which resulted from illegal kickbacks and illegal promotion of drugs for noncovered and nonpayable uses are false claims.

578. From 2005 through present, Defendants knowingly caused false claims to be submitted to the District of Columbia Medicaid program by engaging in an off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify. Defendants' concerted actions to cause the submission of false claims for payment to the District of Columbia violated D.C. Code § 2-308.14(a)(1).

579. Defendants have knowingly caused pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment for Abilify, knowing that such false claims would be submitted to the District of Columbia Medicaid program for reimbursement.

580. Thus, in the furtherance of this scheme, Defendants also caused to be made or used false records or statements to get false claims paid or approved in violation of D.C. Code § 2-308.14(a)(2). For example, each illegal promotion material used to promote a drug off-label was a false record or statement made or used to get a false claim paid or approved.

581. Defendants acted knowingly, as that term is used in the District of Columbia False Claims Act, D.C. Code § 2-308.13(3).

582. Because the District of Columbia would not have paid for the claims resulting from Defendants' illegal schemes, the District of Columbia has been harmed in an amount equal to the value paid by the District of Columbia.

583. The District of Columbia has been damaged as a result of Defendants' conduct in violation of the District of Columbia False Claims Act in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, Relators request:

A. That the Court enter judgment against the Defendants in an amount equal to three times the amount of damages the United States Government has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each action in violation of 31 U.S.C. § 3729, and the costs of this action, with interest, including the costs to the United States Government for its expenses related to this action;

B. That in the event the United States Government intervenes in this action, Relators be awarded 25% of the proceeds of the action or the settlement of any such claim;

C. That in the even the United States Government does not proceed with this action, Relators be awarded 30% of the proceeds of this action or the settlement of any such claim;

D. That the Court enter judgment against the Defendants in the maximum amount of damages available under the State, Commonwealth and District False Claims Acts over which the Court accepts jurisdiction, to include any multipliers provided in such Acts;

E. That the Court enter judgment against the Defendants for the maximum amount of civil penalties in favor of the States, Commonwealths and District of Columbia, together with the States', Commonwealths'' and District's costs of this action;

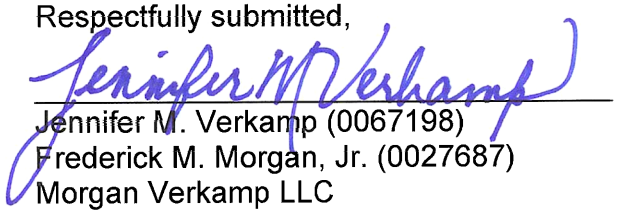
F. That the Relators be awarded, under the State, Commonwealth and District False Claims Acts, the maximum share permitted by law of all amounts recognized by those Acts as a consequence of this action;

G. That the Relators be awarded all damages caused by the Defendant's retaliation and wrongful termination of them, including but not limited to two times the amount of back pay owed to them, interest on such back pay, lost benefits, compensatory and punitive damages, and prejudgment interest to which they are entitled;

H. That Relators be awarded all costs, attorneys' fees, and litigation expenses;

I. That the United States Government, the respective States and Relators receive all relief, both at law and in equity, to which they may reasonably appear entitled.

Respectfully submitted,



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